

DIRECTIVE 2014/53/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL 欧洲议会和理事会第 2014/53/EU 号指令

of 16 April 2014 2014 年 4 月 16 日

on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC 关于协调成员国有关无线电设备投放市场的法律并废除第 1999/5/EC 号指令

(Text with EEA relevance) (与欧洲经济区相关的文本)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, 欧洲议会和欧盟理事会,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof, 考虑到《欧洲联盟运行条约》，特别是其第 114 条，

Having regard to the proposal from the European Commission, 考虑到欧洲委员会的提案，

After transmission of the draft legislative act to the national parliaments, 在将立法法案草案传送至各国议会后，

Having regard to the opinion of the Economic and Social Committee (1), 考虑到经济及社会委员会的意见(1)，

Acting in accordance with the ordinary legislative procedure (2), 按照普通立法程序行事(2)，

Whereas: 鉴于：

(1) Directive 1999/5/EC of the European Parliament and of the Council (3) has been substantially amended several times. Since further amendments are to be made, it should be replaced in the interests of clarity. 欧洲议会和理事会第 1999/5/EC 号指令(3)已历经多次重大修订。鉴于还将进行进一步修订，为清晰起见，应对其予以替换。

(2) Regulation (EC) No 765/2008 of the European Parliament and of the Council (4) lays down rules on the accreditation of conformity assessment bodies, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of the CE marking. 欧洲议会和理事会第 765/2008 号法规 (EC) (4) 规定了合格评定机构的认可规则，为产品的市场监督和来自第三国产品的控制提供了框架，并规定了 CE 标志的一般原则。

(3) Decision No 768/2008/EC of the European Parliament and of the Council (5) lays down common principles and reference provisions intended to apply across sectoral legislation in order to provide a coherent basis for revision or recasts of that legislation. Directive 1999/5/EC should therefore be adapted to that Decision. 欧洲议会和理事会第 768/2008/EC 号决定(5)规定了旨在适用于各部门立法的共同原则和参考条款，以便为该立法的修订或重编提供一致的基础。因此，1999/5/EC 号指令应与该决定相适应。

(4) The essential requirements laid down in Directive 1999/5/EC which are relevant to fixed-line

terminal equipment, i.e. to ensure the protection of health and safety of persons and of domestic animals and the protection of property and an adequate level of electromagnetic compatibility, are appropriately covered by Directive 2014/35/EU of the European Parliament and of the Council ⁽⁶⁾ and Directive 2014/30/EU of the European Parliament and of the Council ⁽⁷⁾. This Directive should therefore not apply to fixed-line terminal equipment. 1999/5/EC 号指令中规定的与固定线路终端设备相关的基本要求，即确保保护人员和家畜的健康与安全、保护财产以及达到适当的电磁兼容水平，已由欧洲议会和理事会 2014/35/EU 号指令⁽⁶⁾和欧洲议会和理事会 2014/30/EU 号指令⁽⁷⁾充分涵盖。因此，本指令不应适用于固定线路终端设备。

(5) Competition issues in the market for terminal equipment are appropriately covered by Commission Directive 2008/63/EC ⁽⁸⁾, in particular through the obligation for national regulatory authorities to ensure the publication of details of technical interface specifications for network access. It is therefore not necessary to include in this Directive requirements facilitating competition in the market for terminal equipment covered by Directive 2008/63/EC. 终端设备市场中的竞争问题已由《欧盟委员会 2008/63/EC 号指令》⁽⁸⁾妥善涵盖，特别是通过要求国家监管机构确保公布网络接入技术接口规范的详细信息来实现。因此，本指令无需纳入促进《2008/63/EC 号指令》所涵盖的终端设备市场竞争的相关要求。

(6) Equipment which intentionally emits or receives radio waves for the purpose of radio communication or radiodetermination makes systematic use of radio spectrum. In order to ensure an efficient use of radio spectrum so as to avoid harmful interference, all such equipment should fall within the scope of this Directive. 为无线电通信或无线电测定目的而有意发射或接收无线电波的设备会系统性地使用无线电频谱。为确保无线电频谱的高效利用并避免有害干扰，所有此类设备均应纳入本指令的适用范围。

(7) The objectives with respect to safety requirements laid down in Directive 2014/35/EU are sufficient to cover radio equipment, and should therefore be the reference and made applicable by virtue of this Directive. In order to avoid unnecessary duplications of provisions other than those concerning such requirements, Directive 2014/35/EU should not apply to radio equipment. 2014/35/EU 号指令中规定的关于安全要求的目标足以涵盖无线电设备，因此应作为本指令的参考并凭借本指令予以适用。为避免除上述要求相关规定外的其他规定出现不必要的重复，2014/35/EU 号指令不应适用于无线电设备。

(8) The essential requirements in the area of electromagnetic compatibility laid down by Directive 2014/30/EU are sufficient to cover radio equipment, and should therefore be the reference and made applicable by virtue of this Directive. In order to avoid unnecessary duplications of provisions other than those concerning essential requirements, Directive 2014/30/EU should not apply to radio equipment. 2014/30/EU 号指令规定的电磁兼容领域基本要求足以涵盖无线电设备，因此应作为本指令的参考并凭借本指令适用。为避免除基本要求相关规定外的不必要重复，2014/30/EU 号指令不应适用于无线电设备。

(9) This Directive should apply to all forms of supply, including distance selling. 本指令应适用于所有供应形式，包括远程销售。

(10) In order to ensure that radio equipment uses the radio spectrum effectively and supports the efficient use of radio spectrum, radio equipment should be constructed so that: in the case

of a transmitter, when the transmitter is properly installed, maintained and used for its intended purpose it generates radio waves emissions that do not create harmful interference, while unwanted radio waves emissions generated by the transmitter (e.g. in adjacent channels) with a potential negative impact on the goals of radio spectrum policy should be limited to such a level that, according to the state of the art, harmful interference is avoided; and, in the case of a receiver, it has a level of performance that allows it to operate as intended and protects it against the risk of harmful interference, in particular from shared or adjacent channels, and, in so doing, supports improvements in the efficient use of shared or adjacent channels. 为确保无线电设备有效利用无线电频谱并支持无线电频谱的高效使用，无线电设备的构造应满足以下要求：对于发射机，当其正确安装、维护并按预定用途使用时，所产生的无线电波发射不应造成有害干扰，同时发射机产生的可能对无线电频谱政策目标产生负面影响的无用无线电波发射（例如在相邻信道中），应限制在根据现有技术水平可避免有害干扰的程度；对于接收机，其性能水平应使其能够按预定方式工作，并能防范有害干扰的风险，特别是来自共享信道或相邻信道的干扰，从而有助于提高共享信道或相邻信道的使用效率。

(11) Although receivers do not themselves cause harmful interference, reception capabilities are an increasingly important factor in ensuring the efficient use of radio spectrum by way of an increased resilience of receivers against harmful interference and unwanted signals on the basis of the relevant essential requirements of Union harmonisation legislation. 尽管接收机本身不会造成有害干扰，但接收能力正成为一个日益重要的因素，这基于欧盟协调立法的相关基本要求，通过提高接收机对有害干扰和无用信号的抗扰度，来确保无线电频谱的高效利用。

(12) Interworking via networks with other radio equipment and connection with interfaces of the appropriate type throughout the Union is necessary in some cases. Interoperability between radio equipment and accessories such as chargers simplifies the use of radio equipment and reduces unnecessary waste and costs. A renewed effort to develop a common charger for particular categories or classes of radio equipment is necessary, in particular for the benefit of consumers and other end-users; this Directive should therefore include specific requirements in that area. In particular, mobile phones that are made available on the market should be compatible with a common charger. 在某些情况下，通过网络与其他无线电设备进行互通，并在整个联盟范围内与相应类型的接口连接是必要的。无线电设备与充电器等配件之间的互操作性简化了无线电设备的使用，并减少了不必要的浪费和成本。有必要重新努力为特定类别或等级的无线电设备开发通用充电器，这尤其有利于消费者和其他终端用户；因此，本指令应包含该领域的具体要求。特别是，投放市场的移动电话应与通用充电器兼容。

(13) The protection of personal data and privacy of users and of subscribers of radio equipment and the protection from fraud may be enhanced by particular features of radio equipment. Radio equipment should therefore in appropriate cases be designed in such a way that it supports those features. 无线电设备的特定功能可以增强对用户和无线电设备订阅者的个人数据及隐私的保护，以及防范欺诈。因此，在适当情况下，无线电设备的设计应能支持这些功能。

(14) Radio equipment can be instrumental in providing access to emergency services. Radio equipment should therefore in appropriate cases be designed in such a way that it supports

the features required for access to those services. 无线电设备在提供紧急服务接入方面可能起到重要作用。因此，在适当情况下，无线电设备的设计应能支持接入这些服务所需的功能。

- (15) Radio equipment is important to the well-being and employment of people with disabilities, who represent a substantial and growing proportion of the population of Member States. Radio equipment should therefore in appropriate cases be designed in such a way that people with disabilities may use it without or with only minimal adaptation. 无线电设备对残疾人的生活福祉和就业至关重要，残疾人在成员国人口中占相当大且不断增长的比例。因此，在适当情况下，无线电设备的设计应能让残疾人无需调整或仅需少量调整就能使用。
- (16) The compliance of some categories of radio equipment with the essential requirements set out in this Directive may be affected by the inclusion of software or modification of its existing software. The user, the radio equipment or a third party should only be able to load software into the radio equipment where this does not compromise the subsequent compliance of that radio equipment with the applicable essential requirements. 某些类别的无线电设备是否符合本指令规定的基本要求，可能会受到软件的纳入或其现有软件修改的影响。只有在不会影响该无线电设备随后符合适用的基本要求的情况下，用户、无线电设备本身或第三方才应能够向该无线电设备加载软件。
- (17) In order to supplement or amend certain non-essential elements of this Directive, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union (TFEU) should be delegated to the Commission. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council. 为补充或修正本指令的某些非必要内容，应将按照《欧洲联盟运行条约》（TFEU）第 290 条通过法案的权力授予欧盟委员会。欧盟委员会在其筹备工作中，包括在专家层面进行适当磋商，这一点尤为重要。欧盟委员会在拟定和起草授权法案时，应确保向欧洲议会和理事会同步、及时且适当地传送相关文件。
- (18) In order to effectively address the needs related to interoperability, protection of personal data and privacy of the user and of the subscriber, protection from fraud, access to emergency services, use by users with a disability or the prevention of non-compliant combinations of radio equipment and software, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the specification of categories or classes of radio equipment that have to comply with one or more of the additional essential requirements set out in this Directive which address those needs. 为有效满足与互操作性、用户及用户个人数据和隐私保护、防欺诈、紧急服务接入、残疾人使用，以及防止无线电设备与软件的不合规组合相关的需求，应依据《欧盟运行条约》第 290 条，将制定相关法规的权力授予欧盟委员会，以明确哪些类别或种类的无线电设备必须遵守本指令中为满足上述需求而规定的一项或多项附加基本要求。
- (19) Verification by radio equipment of the compliance of its combination with software should not be abused in order to prevent its use with software provided by independent parties. The availability to public authorities, manufacturers and users of information on the

compliance of intended combinations of radio equipment and software should contribute to facilitate competition. In order to achieve those objectives, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the specification of categories or classes of radio equipment for which manufacturers have to provide information on the compliance of intended combinations of radio equipment and software with the essential requirements set out in this Directive.无线电设备对其与软件组合的合规性进行验证时，不应被滥用，以防止其被用于独立第三方提供的软件。向公共机构、制造商和用户提供有关无线电设备与软件预期组合合规性的信息，应有助于促进竞争。为实现这些目标，应根据《欧盟运行条约》第 290 条，将制定相关法案的权力授予欧盟委员会，由其明确哪些类别或等级的无线电设备，制造商必须提供其与软件的预期组合符合本指令所列基本要求的相关信息。

(20) A requirement to register in a central system radio equipment to be placed on the market may enhance the efficiency and effectiveness of market surveillance and thereby contribute to ensuring a high level of compliance with this Directive. Such a requirement entails additional burden to economic operators and should therefore be introduced only for those categories of radio equipment where a high level of compliance has not been attained. In order to ensure the application of such a requirement, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the specification of the categories of radio equipment which manufacturers have to register within a central system and the elements of the technical documentation to be provided on the basis of the information on the compliance of radio equipment to be provided by Member States and following an evaluation of the risk of non-implementation of the essential requirements.要求将拟投放市场的无线电设备在中央系统进行注册，可能会提高市场监管的效率和有效性，从而有助于确保高度符合本指令。这一要求会给经济运营商带来额外负担，因此仅应针对那些尚未达到高度合规水平的无线电设备类别引入。为确保这一要求的实施，应根据《欧盟运行条约》第 290 条，将制定相关法规的权力授予欧盟委员会，以明确制造商必须在中央系统注册的无线电设备类别，以及应提供的技术文件内容。这些规定的制定应基于成员国提供的有关无线电设备合规性的信息，并在对基本要求未得到实施的风险进行评估之后进行。

(21) Radio equipment which complies with the relevant essential requirements should be allowed to circulate freely. Such equipment should be allowed to be put into service and used for its intended purpose, where applicable in accordance with rules on authorisations for the use of radio spectrum and the provision of the service concerned.符合相关基本要求的无线电设备应允许自由流通。此类设备应获准投入使用并用于其预定用途，在适用情况下，还应遵循有关无线电频谱使用授权和相关服务提供的规定。

(22) In order to avoid unnecessary barriers to trade in radio equipment within the internal market, Member States should notify, under Directive 98/34/EC of the European Parliament and of the Council ⁽⁹⁾, other Member States and the Commission of their projects in the area of technical regulations, such as radio interfaces, unless those technical regulations allow Member States to comply with binding Union acts such as Commission decisions on the harmonised use of radio spectrum adopted under Decision No 676/2002/EC of the European Parliament and of the Council ⁽¹⁰⁾, or where they correspond to radio equipment which can be put into service and used without restrictions within the Union.为避免内部市场中无线

电设备贸易出现不必要的壁垒，成员国应根据欧洲议会和理事会第 98/34/EC 号指令(9)，将其在无线电接口等技术法规领域的计划通知其他成员国和欧盟委员会，除非这些技术法规允许成员国遵守具有约束力的欧盟法案，例如根据欧洲议会和理事会第 676/2002/EC 号决定(10)通过的关于无线电频谱协调使用的委员会决定，或者这些技术法规对应的无线电设备可在欧盟内部不受限制地投入使用。

(23)The provision of information on the equivalence of regulated radio interfaces and their conditions of use reduces barriers for the access of radio equipment to the internal market. The Commission should therefore assess and establish the equivalence of regulated radio interfaces and make such information available in the form of radio equipment classes.提供有关受监管无线电接口等效性及其使用条件的信息，可减少无线电设备进入内部市场的壁垒。因此，委员会应评估并确定受监管无线电接口的等效性，并以无线电设备类别的形式提供此类信息。

(24)In accordance with Commission Decision 2007/344/EC (11), Member States are to use the Frequency Information System (EFIS) of the European Communications Office (ECO) in order to make comparable information regarding the use of radio spectrum in each Member State available to the public via the internet. Manufacturers can search in EFIS frequency information for all Member States prior to the placing on the market of radio equipment and thereby evaluate whether and under which conditions such radio equipment may be used within each Member State. There is therefore no need to include in this Directive additional provisions, such as prior notification, allowing manufacturers to be informed of the conditions of use of radio equipment using non-harmonised frequency bands.根据欧盟委员会第 2007/344/EC 号决定(11)，成员国应使用欧洲通信办公室（ECO）的频率信息系统（EFIS），以便通过互联网向公众提供有关每个成员国无线电频谱使用情况的可比信息。制造商在将无线电设备投放市场前，可以在 EFIS 中查询所有成员国的频率信息，从而评估此类无线电设备是否可以在每个成员国使用以及在何种条件下使用。因此，本指令无需包含额外条款，如事先通知，以让制造商了解使用非协调频段的无线电设备的使用条件。

(25)For the purpose of promotion of research and demonstration activities it should be possible, in the context of trade fairs, exhibitions and similar events, to display radio equipment which does not comply with this Directive and cannot be placed on the market, on the condition that exhibitors ensure that sufficient information is provided to the visiting public.为促进研究和示范活动，在贸易展览会、博览会及类似活动中，应当允许展示不符合本指令且不能投放市场的无线电设备，前提是参展商确保向参观公众提供充分的信息。

(26)Economic operators should be responsible for the compliance of radio equipment with this Directive, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of health and safety of persons and of domestic animals, and the protection of property, an adequate level of electromagnetic compatibility, an effective and efficient use of radio spectrum and, where necessary, a high level of protection of other public interests, and to guarantee fair competition on the Union market.经济经营者应根据其在供应链中的各自角色，对无线电设备符合本指令负责，以确保对人员和家畜的健康与安全提供高水平保护、对财产提供保护、达到适当的电磁兼容水平、有效且高效地使用无线电频谱，并在必要时为其他公共利益提供高水平保护，同时保障欧盟市场上的公平竞争。

- (27) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they only make available on the market radio equipment which is in conformity with this Directive. It is necessary to provide for a clear and proportionate distribution of obligations which correspond to the role of each economic operator in the supply and distribution chain. 所有参与供应链和分销链的经济运营商都应采取适当措施，确保其投放市场的无线电设备符合本指令的要求。有必要对义务进行清晰且适度的分配，以与供应链和分销链中每个经济运营商的角色相匹配。
- (28) In order to facilitate communication between economic operators, market surveillance authorities and consumers, Member States should encourage economic operators to include a website address in addition to the postal address. 为促进经济经营者、市场监管机构和消费者之间的沟通，成员国应鼓励经济经营者除提供邮政地址外，还应包含一个网站地址。
- (29) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure. Conformity assessment should therefore remain solely the obligation of the manufacturer. 制造商对设计和生产过程有详细的了解，最适合执行合格评定程序。因此，合格评定应始终完全由制造商负责。
- (30) The manufacturer should provide sufficient information on the intended use of the radio equipment so as to allow its use in compliance with the essential requirements. Such information may need to include a description of accessories such as antennas and of components such as software, and specifications of the installation process of the radio equipment. 制造商应提供关于无线电设备预期用途的充分信息，以使其使用符合基本要求。此类信息可能需要包括对天线等附件以及软件等组件的描述，以及无线电设备安装过程的规格说明。
- (31) The requirement laid down in Directive 1999/5/EC to include an EU declaration of conformity with equipment has been found to simplify and to enhance the information and the efficiency of market surveillance. The possibility to provide a simplified EU declaration of conformity has allowed the burden associated with this requirement to be reduced without reduction of its effectiveness, and should therefore be provided for within this Directive. Furthermore, in order to ensure easy and efficient access to an EU declaration of conformity, including a simplified EU declaration of conformity, it should be possible to affix it to the packaging of the radio equipment concerned. 1999/5/EC 号指令中规定的要求，即随设备附上欧盟合格声明，已被证实能够简化和增强信息传递以及市场监管效率。提供简化版欧盟合格声明的可能性，在不降低该要求有效性的前提下减轻了相关负担，因此本指令中应作出相应规定。此外，为确保能便捷高效地获取欧盟合格声明（包括简化版欧盟合格声明），应允许将其附在相关无线电设备的包装上。
- (32) It is necessary to ensure that radio equipment from third countries entering the Union market complies with this Directive, and in particular that appropriate conformity assessment procedures have been carried out by manufacturers with regard to that radio equipment. Provision should therefore be made for importers to make sure that the radio equipment they place on the market complies with the requirements of this Directive and that they do not place on the market radio equipment which does not comply with such requirements or presents a risk. Provision should also be made for importers to make sure that conformity assessment procedures have been carried out and that marking of radio

equipment and documentation drawn up by manufacturers are available for inspection by the competent national authorities.必须确保来自第三国、进入欧盟市场的无线电设备符合本指令，特别是制造商已针对该无线电设备执行了适当的合格评定程序。因此，应规定进口商必须确保其投放市场的无线电设备符合本指令的要求，且不得将不符合此类要求或存在风险的无线电设备投放市场。还应规定进口商必须确保合格评定程序已得到执行，并且制造商拟定的无线电设备标识和文件可供国家主管部门查验。

(33)When placing radio equipment on the market, every importer should indicate on the radio equipment his name, registered trade name or registered trade mark and the postal address at which he can be contacted. Exceptions should be provided for in cases where the size or nature of the radio equipment does not allow it. This includes cases where the importer would have to open the packaging in order to put his name and address on the radio equipment.将无线电设备投放市场时，每个进口商都应在该设备上标明自己的姓名、已注册的商号或注册商标，以及可联系到自己的邮政地址。若因无线电设备的尺寸或性质不允许标注上述信息，则应另有例外规定。这包括进口商为在设备上标注自己的姓名和地址而不得不打开包装的情况。

(34)The distributor makes radio equipment available on the market after it has been placed on the market by the manufacturer or the importer and should act with due care to ensure that its handling of the radio equipment does not adversely affect the compliance of the radio equipment.经销商在制造商或进口商将无线电设备投放市场后，使其在市场上可供购买，并且应当采取适当的谨慎措施，确保其对无线电设备的处理不会对设备的合规性产生不利影响。

(35)Any economic operator that either places radio equipment on the market under his own name or trade mark or modifies radio equipment in such a way that compliance with this Directive may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.任何经济运营商，只要以自己的名义或商标将无线电设备投放市场，或者对无线电设备进行修改而可能影响本指令的合规性，均应被视为制造商，并承担制造商的义务。

(36)Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by the competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the radio equipment concerned.分销商和进口商贴近市场，应当参与国家主管部门开展的市场监督工作，并应准备好积极参与，向这些部门提供与相关无线电设备有关的所有必要信息。

(37)Ensuring traceability of radio equipment throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates market surveillance authorities' task of tracing economic operators who made non-compliant radio equipment available on the market. When keeping the information required under this Directive for the identification of other economic operators, economic operators should not be required to update such information in respect of other economic operators who have either supplied them with radio equipment or to whom they have supplied radio equipment.确保无线电设备在整个供应链中的可追溯性，有助于使市场监管更简单、更高效。高效的追溯系统有助于市场监管机构追踪那些将不合规无线电设备投放市场的经济运营商。

在保存本指令要求的、用于识别其他经济运营商的信息时，不应要求经济运营商更新那些曾向其供应无线电设备或其曾向其供应无线电设备的其他经济运营商的此类信息。

(38) This Directive should be limited to the expression of essential requirements. In order to facilitate conformity assessment with those requirements it is necessary to provide for a presumption of conformity for radio equipment which is in conformity with harmonised standards that are adopted in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council ⁽¹²⁾ for the purpose of expressing detailed technical specifications of those requirements. 本指令应仅限于表述基本要求。为便于对这些要求进行合格评定，对于符合协调标准的无线电设备，有必要推定其合格。这些协调标准是根据欧洲议会和理事会第 1025/2012 号条例（EU）⁽¹²⁾ 采用的，目的是表述这些要求的详细技术规范。

(39) Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy the requirements of this Directive. 《欧盟法规（EU）第 1025/2012 号》规定了针对协调标准的异议程序，当这些标准未完全满足本指令的要求时适用。

(40) In order to enable economic operators to demonstrate and the competent authorities to ensure that radio equipment made available on the market conforms to the essential requirements, it is necessary to provide for conformity assessment procedures. Decision No 768/2008/EC establishes modules for conformity assessment procedures, which include procedures from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. In order to ensure inter-sectoral coherence and to avoid ad-hoc variants, conformity assessment procedures should be chosen from among those modules. 为了使经济经营者能够证明，且主管当局能够确保投放市场的无线电设备符合基本要求，有必要规定合格评定程序。第 768/2008/EC 号决定确立了合格评定程序的模块，其中包括从最宽松到最严格的各种程序，其严格程度与所涉及的风险水平和所需的安全水平相匹配。为确保跨部门的一致性并避免临时变体，合格评定程序应从这些模块中选择。

(41) Manufacturers should draw up an EU declaration of conformity to provide information required under this Directive on the conformity of radio equipment with the requirements of this Directive and of the other relevant Union harmonisation legislation. 制造商应制定欧盟合格声明，以提供本指令要求的关于无线电设备符合本指令及其他相关欧盟协调立法要求的信息。

(42) To ensure effective access to information for market surveillance purposes, the information required to identify all applicable Union acts should be available in a single EU declaration of conformity. In order to reduce the administrative burden on economic operators, that single EU declaration of conformity may be a dossier made up of relevant individual declarations of conformity. 为确保出于市场监督目的能够有效获取信息，识别所有适用的欧盟法规所需的信息应在单一的欧盟合格声明中提供。为减轻经济运营商的行政负担，该单一欧盟合格声明可以由相关的单独合格声明组成的档案。

(43) The CE marking, indicating the conformity of radio equipment, is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the CE marking are set out in Regulation (EC) No 765/2008. Rules governing the

affixing of the CE marking should be laid down in this Directive. CE 标志表明无线电设备的合规性，它是包括广义上的合规性评估在内的整个过程的直观体现。规范 CE 标志的一般原则在《(EC)第 765/2008 号条例》中作出了规定。关于 CE 标志的粘贴规则应在本指令中予以制定。

(44)The requirement to affix the CE marking on products is important for the information of consumers and public authorities. The possibility laid down in Directive 1999/5/EC to affix a reduced CE mark on small-sized equipment, provided that it remains visible and legible, has allowed the application of that requirement to be simplified without reducing its effectiveness, and should therefore be included in this Directive.在产品上粘贴 CE 标志的要求对于消费者和公共机构了解信息而言十分重要。1999/5/EC 号指令中规定，在小型设备上可粘贴缩小版的 CE 标志，只要该标志保持清晰可见且易于辨认即可。这一规定简化了上述要求的实施，同时又未降低其效力，因此应纳入本指令。

(45)The requirement laid down in Directive 1999/5/EC to affix the CE marking on the packaging of equipment has been found to simplify the task of market surveillance, and should therefore be included in this Directive.1999/5/EC 号指令中规定的在设备包装上粘贴 CE 标志的要求，已被证实能简化市场监管工作，因此应纳入本指令。

(46)Member States should take appropriate measures to ensure that radio equipment may be made available on the market only if, when properly installed and maintained and used for its intended purpose, it complies with the essential requirements set out in this Directive, and, in the case of the essential requirement to ensure the protection of the health and safety of persons and of domestic animals and the protection of property, also under conditions of use which can be reasonably foreseen. Radio equipment should be considered as non-compliant with that essential requirement only under conditions of use which can be reasonably foreseen, that is when such use could result from lawful and readily predictable human behaviour.成员国应采取适当措施，确保无线电设备只有在正确安装、维护并按预定用途使用时符合本指令规定的基本要求，且对于确保人员和家畜健康安全以及财产保护的基本要求，在可合理预见的使用条件下也能满足时，方可投放市场。只有在可合理预见的使用条件下——即这种使用可能源于合法且易于预见的人类行为时，无线电设备才应被视为不符合该基本要求。

(47)In view of the rapid pace of technological change towards a paperless environment, where radio equipment is fitted with an integral screen, the Commission should examine, as part of a review of the operation of this Directive, the feasibility of replacing the requirements for affixing: the manufacturer's name, registered trade name or registered trade mark and a single point or postal address at which they can be contacted, CE marking and EU declaration of conformity with either a function whereby such information is automatically displayed upon starting up the radio equipment, or a function allowing the end-user to select the display of the relevant information. Furthermore, as part of that examination of feasibility, where radio equipment fitted with an integral screen operates from an integral battery which does not hold an initial charge, the Commission should also consider the use of removable transparent integral screen covering labels which would display the same information.鉴于技术正朝着无纸环境快速变革，且无线电设备都配备了内置屏幕，欧盟委员会应在审查本指令的实施情况时，研究用以下两种功能替代粘贴要求的可行性：一是无线电设备启动时自动显示相关信息的功能，二是允许最终用户选择显示相关信息的

功能，这些信息包括制造商名称、注册商号或注册商标，以及可联系到他们的单一地点或邮政地址、CE 标志和欧盟符合性声明。此外，在该可行性研究中，对于配备内置屏幕且使用初始无电内置电池的无线电设备，欧盟委员会还应考虑使用可移除的透明内置屏幕覆盖标签来显示上述相同信息。

(48) Certain conformity assessment procedures set out in this Directive require the intervention of conformity assessment bodies, which are notified by the Member States to the Commission. 本指令中规定的某些合格评定程序需要合格评定机构的介入，这些机构由成员国向委员会通报。

(49) Experience has shown that the criteria set out in Directive 1999/5/EC that conformity assessment bodies have to fulfil to be notified to the Commission are not sufficient to ensure a uniformly high level of performance of notified bodies throughout the Union. It is, however, essential that all notified bodies perform their functions to the same level and under conditions of fair competition. That requires the setting of obligatory requirements for conformity assessment bodies wishing to be notified in order to provide conformity assessment services. 经验表明，1999/5/EC 号指令中规定的合格评定机构为获得向委员会通报所必须满足的标准，并不足以确保整个欧盟范围内被通报机构都能保持统一的高水平表现。然而，所有被通报机构必须在公平竞争的条件下以相同水平履行其职能，这一点至关重要。这就要求为希望获得通报以提供合格评定服务的合格评定机构设定强制性要求。

(50) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards, it should be presumed to comply with the corresponding requirements set out in this Directive. 如果某一合格评定机构表明其符合协调标准中规定的标准，则应推定其符合本指令中规定的相应要求。

(51) In order to ensure a consistent level of conformity assessment quality it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies. 为确保合格评定质量的一致性水平，还需要为公告机构以及参与公告机构评定、公告和监督工作的其他机构设定要求。

(52) The system set out in this Directive should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification. 本指令所规定的体系应辅予以《(EC)第 765/2008 号条例》中规定的认可体系。由于认可是验证合格评定机构能力的重要手段，因此它也应用于通报目的。

(53) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in conformity certificates, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out that evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements. 《欧洲共同体法规》(EC) 第 765/2008 号所规定的透明认证，能确保合格

证书具备必要的可信度，欧盟各国公共当局应将其视为证明合格评定机构技术能力的首选方式。不过，国家主管部门可能认为自身拥有开展该评估的适当手段。在这种情况下，为确保其他国家主管部门所做评估具有适当的可信度，它们应向欧盟委员会及其他成员国提供必要的书面证据，以证明所评估的合格评定机构符合相关法规要求。

(54)Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for radio equipment to be placed on the Union market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified and the monitoring of bodies already notified cover also activities carried out by subcontractors and subsidiaries.合格评定机构经常将与其合格评定相关的部分活动分包出去，或求助于子公司。为确保投放欧盟市场的无线电设备达到所需的保护水平，合格评定分包商和子公司在执行合格评定任务时，必须满足与被通知机构相同的要求。因此，对拟被通知机构的能力和表现的评定，以及对已被通知机构的监督，都必须涵盖分包商和子公司所开展的活动，这一点至关重要。

(55)It is necessary to increase the efficiency and transparency of the notification procedure and, in particular, to adapt it to new technologies so as to enable online notification.有必要提高通知程序的效率和透明度，特别是使其适应新技术，以便能够进行在线通知。

(56)Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.由于公告机构可在整个欧盟范围内提供服务，因此宜为其他成员国和委员会提供对公告机构提出异议的机会。因此，重要的是规定一个期限，在此期间内，关于合格评定机构能力的任何疑问或担忧都可在其作为公告机构开始运作之前得到澄清。

(57)In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.为了提高竞争力，公告机构在执行合格评定程序时，绝不能给经济运营商造成不必要的负担，这一点至关重要。出于同样的原因，同时也为了确保经济运营商得到平等对待，必须保证合格评定程序在技术应用上的一致性。而实现这一点的最佳方式是公告机构之间开展适当的协调与合作。

(58)In order to ensure legal certainty, it is necessary to clarify that rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008 apply to radio equipment covered by this Directive. This Directive should not prevent Member States from choosing the competent authorities to carry out those tasks.为确保法律确定性，有必要明确，第 765/2008 号条例（EC）中规定的关于欧盟市场监督以及对进入欧盟市场的产品进行管控的规则适用于本指令所涵盖的无线电设备。

本指令不应阻止成员国选择主管当局来执行这些任务。

- (59) Directive 1999/5/EC already provides for a safeguard procedure which applies only in the event of disagreement between Member States over measures taken by a Member State. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard procedure, with a view to making it more efficient and drawing on the expertise available in Member States. 1999/5/EC 号指令已规定了一项保障程序，该程序仅在成员国之间就某一成员国所采取的措施存在分歧时适用。为提高透明度并缩短处理时间，有必要完善现有的保障程序，以提高其效率并利用成员国现有的专业知识。
- (60) The decisions of the Commission adopted under Decision No 676/2002/EC may include conditions for the availability and efficient use of radio spectrum which may have as a consequence the limitation of the total number of items of radio equipment put into service, such as a 'sunset' date, a maximum penetration rate or a maximum number of items of radio equipment in each Member State or throughout the Union. Those conditions enable the market to be opened up to new radio equipment while limiting the risk of harmful interference by accumulation of an excessive number of items of radio equipment put into service, even though that equipment individually complies with the essential requirements set out in this Directive. Infringing such conditions may create a risk to the essential requirements, particularly a risk of harmful interference. 委员会根据第 676/2002/EC 号决定通过的各项决定，可包含有关无线电频谱可用性及高效使用的条件，这些条件可能导致投入使用的无线电设备总数受到限制，例如设定“日落”日期、最高渗透率，或每个成员国及整个联盟内的无线电设备最大数量。这些条件有助于为新型无线电设备开放市场，同时降低因投入使用的无线电设备数量过多累积而产生有害干扰的风险，即便这些设备单独来看符合本指令规定的基本要求。违反此类条件可能会对基本要求构成风险，尤其是产生有害干扰的风险。
- (61) The existing system should be supplemented by a procedure under which interested parties are informed of measures intended to be taken with regard to radio equipment presenting a risk to the health or safety of persons or to other aspects of public interest protection covered by this Directive. It should also allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such equipment. 现有系统应辅以一项程序，根据该程序，利益相关方应被告知针对对人体健康或安全或本指令所涵盖的公共利益保护的其他方面构成风险的无线电设备拟采取的措施。该程序还应允许市场监督机构与相关经济运营商合作，针对此类设备在更早阶段采取行动。
- (62) Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard. 如果成员国与委员会就某一成员国所采取措施的正当性达成一致，则不应要求委员会进一步参与，除非不遵守规定可归因于协调标准的缺陷。
- (63) In order to ensure uniform conditions for the implementation of this Directive, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽¹³⁾. 为确保本指令的统一实施，应赋予委员会执行权。这些权力应依照欧洲议会

和理事会第 182/2011 号条例（欧盟）(13)行使。

- (64)The advisory procedure should be used for the adoption of implementing acts specifying how to present information in cases of restrictions on putting into service or of existing requirements for authorisation of use; and requesting the notifying Member State to take the necessary corrective measures in respect of a notified body that does not meet or no longer meets the requirements for its notification.在通过实施法案时，应采用咨询程序。这些实施法案需明确在限制投入使用或存在使用授权要求的情况下如何呈现信息；并要求通知成员国对不符合或不再符合其通知要求的 notified body 采取必要的纠正措施。
- (65)The examination procedure should be used for the adoption of implementing acts: determining whether certain categories of electrical or electronic products meet the definition of ‘radio equipment’; laying down the operational rules for making the information on compliance available; laying down the operational rules for registration and the operational rules for affixing the registration number on radio equipment; and establishing the equivalence between notified radio interfaces and assigning a radio equipment class. It should also be used with respect to compliant radio equipment which presents a risk to the health or safety of persons or to other aspects of public interest protection.制定实施法案时应采用以下审查程序：确定某些类别的电气或电子产品是否符合“无线电设备”的定义；制定合规信息公开的操作规则；制定注册操作规则以及在无线电设备上粘贴注册号的操作规则；确定已通报无线电接口之间的等效性并分配无线电设备类别。对于对人员健康或安全或公共利益保护的其他方面构成风险的合规无线电设备，也应采用该审查程序。
- (66)The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to compliant radio equipment which presents a risk to the health or safety of persons, imperative grounds of urgency so require.在涉及合规无线电设备对人员健康或安全构成风险且有充分理由的情况下，若存在紧急的迫切理由，委员会应通过可立即适用的实施法案。
- (67)In line with established practice, the committee set up by this Directive can play a useful role in examining matters concerning the application of this Directive raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.按照既定惯例，本指令设立的委员会可根据其议事规则，在审查由主席或成员国代表提出的与本指令适用相关的事项方面发挥有益作用。
- (68)When matters relating to this Directive, other than its implementation or infringements, are being examined, i.e. in a Commission expert group, the European Parliament should in line with existing practice receive full information and documentation and, where appropriate, an invitation to attend such meetings.在审查与本指令相关但不涉及其实施或侵权的事项时，即在世贸组织专家小组中，欧洲议会应按照现行惯例获得完整的信息和文件，并在适当情况下受邀参加此类会议。
- (69)The Commission should, by means of implementing acts and, given their special nature, acting without the application of Regulation (EU) No 182/2011, determine whether measures taken by Member States in respect of non-compliant radio equipment are justified or not.委员会应通过实施法案，并鉴于其特殊性质，在不适用第 182/2011 号条例（欧盟）的情况下，判定成员国针对不合格无线电设备所采取的措施是否合理。
- (70)The Member States should lay down rules on penalties applicable to infringements of the

provisions of national law adopted pursuant to this Directive and ensure that those rules are enforced. The penalties provided for should be effective, proportionate and dissuasive. 成员国应制定关于适用于违反根据本指令通过的国内法规定的处罚规则，并确保这些规则得到执行。所规定的处罚应有效、适当且具有威慑力。

(71) It is necessary to provide for transitional arrangements that allow the making available on the market and putting into service of radio equipment that has already been placed on the market in accordance with Directive 1999/5/EC. 有必要做出过渡性安排，允许那些已根据 1999/5/EC 号指令投放市场的无线电设备继续在市场上供应和投入使用。

(72) The European Data Protection Supervisor has been consulted. 已咨询欧洲数据保护监督员。

(73) Since the objective of this Directive, namely to ensure that radio equipment made available on the market fulfils requirements providing a high level of protection of health and safety, adequate level of electromagnetic compatibility and an effective and efficient use of radio spectrum so as to avoid harmful interference while guaranteeing the proper functioning of the internal market, cannot be sufficiently achieved by the Member States but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective. 本指令的目标是确保投放市场的无线电设备满足以下要求：提供高水平的健康和安全保护、适当的电磁兼容性水平，以及对无线电频谱的有效且高效利用，从而在保证内部市场正常运作的同时避免有害干扰。由于这一目标无法由成员国充分实现，而考虑到其规模和影响，在欧盟层面能更好地实现，因此欧盟可根据《欧洲联盟条约》第 5 条规定的辅助性原则采取措施。根据该条规定的比例原则，本指令的内容不超出实现上述目标所必需的范围。

(74) Directive 1999/5/EC should be repealed. 应废除第 1999/5/EC 号指令。

(75) In accordance with the Joint Political Declaration of 28 September 2011 of Member States and the Commission on explanatory documents ⁽¹⁴⁾, Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments. With regard to this Directive, the legislator considers the transmission of such documents to be justified. 根据成员国与委员会 2011 年 9 月 28 日关于解释性文件的《联合政治宣言》(14)，成员国承诺在有正当理由的情况下，在通知其转换措施时，附上一份或多份文件，说明指令各组成部分与国家转换工具相应部分之间的关系。关于本指令，立法者认为提交此类文件是有正当理由的。

HAVE ADOPTED THIS DIRECTIVE: 通过本指令：

CHAPTER I 第一章

GENERAL PROVISIONS 一般规定

Article 1 第 1 条

Subject matter and scope 适用范围和标的事项

1. This Directive establishes a regulatory framework for the making available on the market and putting into service in the Union of radio equipment.1. 本指令为在欧盟境内将无线电设备投放市场和投入使用建立了监管框架。

2. This Directive shall not apply to equipment listed in Annex I.2. 本指令不适用于附件 I 所列设备。

3. This Directive shall not apply to radio equipment exclusively used for activities concerning public security, defence, State security, including the economic well-being of the State in the case of activities pertaining to State security matters, and the activities of the State in the area of criminal law.3. 本指令不适用于专门用于以下活动的无线电设备：公共安全、国防、国家安全（包括与国家安全事务相关的活动中涉及国家经济福祉的情况）以及国家在刑法领域的活动。

4. Radio equipment falling within the scope of this Directive shall not be subject to Directive 2014/35/EU, except as set out in point (a) of Article 3(1) of this Directive.4. 属于本指令范围内的无线电设备不受 2014/35/EU 号指令约束，但本指令第 3 条第（1）款（a）项规定的除外。

Article 2 第 2 条

Definitions 定义

1. For the purposes of this Directive, the following definitions apply:1. 就本指令而言，适用以下定义：

(1)'radio equipment' means an electrical or electronic product, which intentionally emits and/or receives radio waves for the purpose of radio communication and/or radiodetermination, or an electrical or electronic product which must be completed with an accessory, such as antenna, so as to intentionally emit and/or receive radio waves for the purpose of radio communication and/or radiodetermination;"无线电设备"是指有意发射和/或接收无线电波以用于无线电通信和/或无线电测定的电气或电子产品，或必须配备天线等附件才能有意发射和/或接收无线电波以用于无线电通信和/或无线电测定的电气或电子产品；

(2)'radio communication' means communication by means of radio waves;"无线电通信"指通过无线电波进行的通信；

(3)'radiodetermination' means the determination of the position, velocity and/or other characteristics of an object, or the obtaining of information relating to those parameters, by means of the propagation properties of radio waves;"无线电测定"是指通过无线电波的传播特性来确定物体的位置、速度和/或其他特性，或获取与这些参数相关的信息；

(4)'radio waves' means electromagnetic waves of frequencies lower than 3 000 GHz, propagated in space without artificial guide;"无线电波"是指频率低于 3000 吉赫兹、在空间中无人工引导传播的电磁波；

(5)'radio interface' means the specification of the regulated use of radio spectrum;"无线电接口"指对无线电频谱的规范使用作出的规定；

(6)'radio equipment class' means a class identifying particular categories of radio equipment which, under this Directive, are considered similar and those radio interfaces for which the

radio equipment is designed;“无线电设备类别”指的是根据本指令,标识被视为相似的特定无线电设备类别以及该无线电设备所设计的无线电接口的类别。

(7)‘harmful interference’ means harmful interference as defined in point (r) of Article 2 of Directive 2002/21/EC of the European Parliament and of the Council ⁽¹⁵⁾;“有害干扰”指的是欧洲议会和理事会第 2002/21/EC 号指令第 2 条(r)点所定义的有害干扰⁽¹⁵⁾;

(8)‘electromagnetic disturbance’ means electromagnetic disturbance as defined in point 5 of Article 3(1) of Directive 2014/30/EU;“电磁干扰”指的是《2014/30/EU 号指令》第 3 条第 (1) 款第 5 点所定义的电磁干扰;

(9)‘making available on the market’ means any supply of radio equipment for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;“投放市场”是指在商业活动过程中,为在联盟市场进行分销、消费或使用而提供任何无线电设备,无论是否以支付为回报或免费提供。

(10)‘placing on the market’ means the first making available of radio equipment on the Union market;“投放市场”指首次将无线电设备投放至欧盟市场;

(11)‘putting into service’ means the first use of radio equipment in the Union by its end-user;“投入使用”是指最终用户在联盟境内首次使用无线电设备;

(12)‘manufacturer’ means any natural or legal person who manufactures radio equipment or has radio equipment designed or manufactured, and markets that equipment under his name or trade mark;“制造商”指任何自然人或法人,其制造无线电设备,或委托设计、制造无线电设备,并以自己的名义或商标销售该设备。

(13)‘authorised representative’ means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;“授权代表”指在联盟内设立的任何自然人或法人,该自然人或法人已获得制造商的书面授权,代表其执行特定任务。

(14)‘importer’ means any natural or legal person established within the Union who places radio equipment from a third country on the Union market;“进口商”指在联盟内设立的任何自然人或法人,其将来自第三国的无线电设备投放至联盟市场;

(15)‘distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes radio equipment available on the market;“经销商”指供应链中除制造商或进口商外,将无线电设备投放市场的任何自然人或法人;

(16)‘economic operators’ means the manufacturer, the authorised representative, the importer and the distributor;“经济经营者”指制造商、授权代表、进口商和分销商;

(17)‘technical specification’ means a document that prescribes technical requirements to be fulfilled by radio equipment;“技术规范”指规定无线电设备需满足的技术要求的文件;

(18)‘harmonised standard’ means harmonised standard as defined in point (c) of point 1 of Article 2 of Regulation (EU) No 1025/2012;“协调标准”指的是《欧盟条例》(第 1025/2012 号)第 2 条第 1 点 (c) 项所定义的协调标准;

(19)‘accreditation’ means accreditation as defined in point 10 of Article 2 of Regulation (EC) No 765/2008;“认证”指的是《(EC)第 765/2008 号条例》第 2 条第 10 点所定义的认证;

- (20) 'national accreditation body' means national accreditation body as defined in point 11 of Article 2 of Regulation (EC) No 765/2008; "国家认可机构"是指《(欧盟)第 765/2008 号条例》第 2 条第 11 点所定义的国家认可机构;
- (21) 'conformity assessment' means the process demonstrating whether the essential requirements of this Directive relating to radio equipment have been fulfilled; "合格评定"是指证明本指令中与无线电设备相关的基本要求是否得到满足的过程;
- (22) 'conformity assessment body' means a body that performs conformity assessment activities; "合格评定机构"是指从事合格评定活动的机构;
- (23) 'recall' means any measure aimed at achieving the return of radio equipment that has already been made available to the end-user; "召回"是指旨在使已向最终用户提供的无线电设备返回的任何措施;
- (24) 'withdrawal' means any measure aimed at preventing radio equipment in the supply chain from being made available on the market; "撤回"是指旨在防止供应链中的无线电设备进入市场的任何措施;
- (25) 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products; "欧盟协调立法"是指任何协调产品销售条件的欧盟立法;
- (26) 'CE marking' means a marking by which the manufacturer indicates that the radio equipment is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing. "CE 标志"是指制造商用以表明无线电设备符合欧盟协调立法中规定的适用要求(该立法规定了 CE 标志的粘贴)的一种标志。

2. The Commission may adopt implementing acts to determine whether certain categories of electrical or electronic products meet the definition set out in point 1 of paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 45(3).2. 委员会可通过实施法案,以确定某些类别的电气或电子产品是否符合本条第 1 款第 1 项规定的定义。这些实施法案应依照第 45 条第 3 款所述的审查程序通过。

Article 3 第 3 条

Essential requirements 基本要求

1. Radio equipment shall be constructed so as to ensure: 1. 无线电设备的构造应确保:
- (a) (a) the protection of health and safety of persons and of domestic animals and the protection of property, including the objectives with respect to safety requirements set out in Directive 2014/35/EU, but with no voltage limit applying; 保护人员和家畜的健康与安全,以及保护财产,包括指令 2014/35/EU 中规定的有关安全要求的目标,但不适用电压限制;
- (b) an adequate level of electromagnetic compatibility as set out in Directive 2014/30/EU. 符合 2014/30/EU 号指令规定的足够水平的电磁兼容性。

2. Radio equipment shall be so constructed that it both effectively uses and supports the efficient use of radio spectrum in order to avoid harmful interference.2. 无线电设备的构造应能确保其既能有效使用无线电频谱,又能支持无线电频谱的高效利用,以避免有害干扰。

3. Radio equipment within certain categories or classes shall be so constructed that it complies with the following essential requirements:3. 特定类别或等级的无线电设备的构造应符合以下基本要求:

(a) (a) radio equipment interworks with accessories, in particular with common chargers;无线电设备可与附件交互工作,特别是与通用充电器;

(b)radio equipment interworks via networks with other radio equipment;无线电设备通过网络与其他无线电设备互通;

(c) (c) radio equipment can be connected to interfaces of the appropriate type throughout the Union;无线电设备可在整个联盟范围内连接到相应类型的接口;

(d) (d) radio equipment does not harm the network or its functioning nor misuse network resources, thereby causing an unacceptable degradation of service;无线电设备不会损害网络或其功能,也不会滥用网络资源,从而导致不可接受的服务质量下降;

(e)radio equipment incorporates safeguards to ensure that the personal data and privacy of the user and of the subscriber are protected;无线电设备包含保障措施,以确保用户和用户的个人数据及隐私得到保护;

(f)radio equipment supports certain features ensuring protection from fraud;无线电设备支持某些功能,以确保免受欺诈侵害;

(g) (g) radio equipment supports certain features ensuring access to emergency services;无线电设备支持某些功能,以确保能接入紧急服务;

(h) (h) 无线电设备支持某些radio equipment supports certain features in order to facilitate its些功能,以方便残障用户使用use by users with a disability;无线电设备支持某些功能,以便为残障用户使用该设备提供便利;

(i) (i) 无线电设备支持某些radio equipment supports certain features in order to ensure that功能,以确保只有在已证明software can only be loaded into the radio equipment where the无线电设备与软件的组合符合compliance of the combination of the radio equipment and合要求的情况下,才能将软software has been demonstrated.无线电设备支持某些功能,以件加载到该无线电设备中。确保软件只能加载到已证明无线电设备与软件组合合规性的无线电设备中。

The Commission shall be empowered to adopt delegated acts in accordance with Article 44 specifying which categories or classes of radio equipment are concerned by each of the requirements set out in points (a) to (i) of the first subparagraph of this paragraph.委员会应有权根据第 44 条通过授权法案,明确本款第一项(a)至(i)点所列各项要求分别涉及哪些类别或等级的无线电设备。

Article 4 第 4 条

Provision of information on the compliance of combinations of radio equipment and software 关于无线电设备与软件组合合规性的信息提供

1. Manufacturers of radio equipment and of software allowing radio equipment to be used as intended shall provide the Member States and the Commission with information on the compliance of intended combinations of radio equipment and software with the essential requirements set out in Article 3. Such information shall result from a conformity assessment carried out in accordance with Article 17, and shall be given in the form of a statement of compliance which includes the elements set out in Annex VI. Depending on the specific combinations of radio equipment and software, the information shall precisely identify the radio equipment and the software which have been assessed, and it shall be continuously updated.1. 无线电设备制造商以及允许无线电设备按预期使用的软件制造商, 应向成员国和委员会提供有关无线电设备与软件的预期组合符合第 3 条规定的基本要求的消息。此类信息应源自根据第 17 条进行的合格评定, 并应以包含附件六所列要素的合格声明形式提供。根据无线电设备与软件的具体组合情况, 该信息应准确识别已评估的无线电设备和软件, 且应持续更新。

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 44 specifying which categories or classes of radio equipment are concerned by the requirement set out in paragraph 1 of this Article.2. 委员会应有权根据第 44 条通过授权法案, 明确哪些类别或等级的无线电设备适用本条第 1 款规定的要求。

3. The Commission shall adopt implementing acts laying down the operational rules for making the information on compliance available for the categories and classes specified by the delegated acts adopted pursuant to paragraph 2 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 45(3).3. 委员会应通过实施法案, 为根据本条第 2 款通过的授权法案所规定的类别和等级制定合规信息公开的操作规则。这些实施法案应依照第 45 条第 3 款所述的审查程序通过。

Article 5 第 5 条

Registration of radio equipment types within some categories 某些类别内无线电设备类型的注册

1. As from 12 June 2018, manufacturers shall register radio equipment types within categories of radio equipment affected by a low level of compliance with the essential requirements set out in Article 3 within a central system referred to in paragraph 4 of this Article prior to radio equipment within those categories being placed on the market. When registering such radio equipment types, manufacturers shall provide some, or where justified all, elements of the technical documentation listed in points (a), (d), (e), (f), (g), (h) and (i) of Annex V. The Commission shall allocate to each registered radio equipment type a registration number, which manufacturers shall affix on radio equipment placed on the market.1. 自 2018 年 6 月 12 日起, 对于那些在符合第 3 条规定的基本要求方面达标率较低的无线电设备类别, 制造商在将这些类别的无线电设备投放市场前, 应在本条第 4 款提及的中央系统中对无线电设

备型号进行注册。注册此类无线电设备型号时，制造商应提供附件五(a)、(d)、(e)、(f)、(g)、(h)和(i)点所列技术文件的部分内容，有正当理由时应提供全部内容。欧盟委员会应给每个已注册的无线电设备型号分配一个注册号，制造商应将该注册号粘贴在投放市场的无线电设备上。

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 44 specifying which categories of radio equipment are concerned by the requirement set out in paragraph 1 of this Article, and the elements of the technical documentation to be provided, taking into account the information on the compliance of radio equipment provided by Member States in accordance with Article 47(1) and following an evaluation of the risk of non-implementation of the essential requirements. 2. 委员会应有权根据第 44 条通过授权法案，明确哪些类别的无线电设备适用本条第 1 款规定的要求，以及应提供的技术文件的内容，同时考虑到成员国根据第 47 条第 1 款提供的关于无线电设备合规性的信息，并在对基本要求未得到实施的风险进行评估之后。

3. The Commission shall adopt implementing acts laying down the operational rules for registration and the operational rules for affixing the registration number on radio equipment for the categories specified by the delegated acts adopted pursuant to paragraph 2 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 45(3). 3. 对于根据本条第 2 款通过的授权法案所规定的类别，委员会应通过实施法案，制定注册操作规则以及在无线电设备上粘贴注册号的规则。这些实施法案应依照第 45 条第 3 款所述的审查程序通过。

4. The Commission shall make available a central system allowing manufacturers to register the required information. That system shall ensure appropriate control of access to information of confidential nature. 4. 委员会应提供一个中央系统，允许制造商注册所需信息。该系统应确保对机密性质信息的访问进行适当控制。

5. Following the date of application of a delegated act adopted pursuant to paragraph 2 of this Article, the reports prepared in accordance with Article 47(1) and (2) shall evaluate its impacts. 5. 在根据本条第 2 款通过的授权法案的适用日期之后，按照第 47 条第 1 款和第 2 款编制的报告应对其影响进行评估。

Article 6 第 6 条

Making available on the market 投放市场

Member States shall take appropriate measures to ensure that radio equipment is made available on the market only if it complies with this Directive. 成员国应采取适当措施，确保只有符合本指令的无线电设备才能在市场上销售。

Article 7 第 7 条

Putting into service and use 投入使用和运行

Member States shall allow the putting into service and use of radio equipment if it complies with this Directive when it is properly installed, maintained and used for its

intended purpose. Without prejudice to their obligations under Decision No 676/2002/EC and to the conditions attached to authorisations for the use of frequencies in conformity with Union law, in particular under Article 9(3) and (4) of Directive 2002/21/EC, Member States may only introduce additional requirements for the putting into service and/or use of radio equipment for reasons related to the effective and efficient use of the radio spectrum, to the avoidance of harmful interference, to the avoidance of electromagnetic disturbances or to public health. 成员国应允许符合本指令的无线电设备投入使用和运行,前提是设备经过正确安装、维护,并按预定用途使用。在不影响其根据第 676/2002/EC 号决定所承担的义务,以及不违反符合欧盟法律(特别是第 2002/21/EC 号指令第 9 条第 3 款和第 4 款)的频率使用授权所附条件的情况下,成员国仅可出于与无线电频谱的有效及高效使用、避免有害干扰、避免电磁干扰或公共健康相关的原因,对无线电设备的投入使用和/或运行提出额外要求。

Article 8 第 8 条

Notification of radio interface specifications and assignment of radio equipment classes 无线电接口规范的通知及无线电设备类别的分配

1. Member States shall notify, in accordance with the procedure set out in Directive 98/34/EC, the radio interfaces which they intend to regulate except: 1. 成员国应按照第 98/34/EC 号指令规定的程序,通报其拟规范的无线电接口,但以下情况除外:

(a) (a) the radio interfaces which fully and without any deviation comply with the Commission decisions on the harmonised use of radio spectrum adopted pursuant to Decision No 676/2002/EC; and 完全且毫无偏差地符合委员会根据第 676/2002/EC 号决定通过的关于无线电频谱协调使用的决定的无线电接口; 以及

(b) the radio interfaces which, in accordance with implementing acts adopted pursuant to paragraph 2 of this Article, correspond to radio equipment which can be put into service and used without restrictions within the Union. 根据本条第 2 款通过的实施法案,这些无线电接口对应的无线电设备可在欧盟境内不受限制地投入使用和运行。

2. The Commission shall adopt implementing acts establishing the equivalence between notified radio interfaces and assigning a radio equipment class, details of which shall be published in the *Official Journal of the European Union*. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 45(3). 2. 委员会应通过实施法案,确定已通报无线电接口之间的等效性并分配无线电设备类别,其详细内容应在《欧盟官方公报》上公布。这些实施法案应根据第 45 条第 (3) 款所述的审查程序通过。

Article 9 第 9 条

Free movement of radio equipment 无线电设备的自由流通

1. Member States shall not impede, for reasons relating to aspects covered by this Directive, the making available on the market in their territory of radio equipment

which complies with this Directive.1. 成员国不得因本指令所涵盖方面的相关原因，阻碍符合本指令的无线电设备在其领土内的市场投放。

2. At trade fairs, exhibitions and similar events, Member States shall not create any obstacles to the display of radio equipment which does not comply with this Directive, provided that a visible sign clearly indicates that such radio equipment may not be made available on the market or put into service until it has been brought into conformity with this Directive. Demonstration of radio equipment may only take place provided that adequate measures, as prescribed by Member States, have been taken to avoid harmful interference, electromagnetic disturbances and risk to the health or safety of persons or of domestic animals or to property.2. 在贸易展会、展览会及类似活动中，成员国不得对展示不符合本指令的无线电设备设置任何障碍，但前提是须有清晰可见的标识明确表明，此类无线电设备在符合本指令要求之前，不得投放市场或投入使用。无线电设备的演示活动仅在采取了成员国规定的充分措施以避免有害干扰、电磁扰动以及对人员、家畜健康或安全或财产构成风险的情况下方可进行。

CHAPTER II 第二章

OBLIGATIONS OF ECONOMIC OPERATORS 经济运营商的义务

Article 10 第10条

Obligations of manufacturers 制造商的义务

1. When placing their radio equipment on the market, manufacturers shall ensure that it has been designed and manufactured in accordance with the essential requirements set out in Article 3.1. 制造商在将其无线电设备投放市场时，应确保该设备的设计和制造符合第3条规定的基本要求。

2. Manufacturers shall ensure that radio equipment shall be so constructed that it can be operated in at least one Member State without infringing applicable requirements on the use of radio spectrum.2. 制造商应确保无线电设备的构造使其至少能在一个成员国境内运行，且不违反有关无线电频谱使用的适用要求。

3. Manufacturers shall draw up the technical documentation referred to in Article 21 and carry out the relevant conformity assessment procedure referred to in Article 17 or have it carried out.3. 制造商应编制第21条所述的技术文件，并执行第17条所述的相关合格评定程序，或委托他人执行该程序。

Where compliance of radio equipment with the applicable requirements has been demonstrated by that conformity assessment procedure, manufacturers shall draw up an EU declaration of conformity and affix the CE marking. 如果通过该合格评定程序证明无线电设备符合适用要求，制造商应拟定欧盟合格声明并加贴CE标志。

4. Manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after the radio equipment has been placed on the market.4. 制造商应在无线电设备投放市场后，将技术文件和欧盟符合性声明保存10年。

5. Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Directive. Changes in radio equipment design or characteristics and changes in the harmonised standards or in other technical specifications by reference to which conformity of radio equipment is declared shall be adequately taken into account. 5. 制造商应确保制定相关程序，使批量生产的产品持续符合本指令的要求。无线电设备设计或特性的变更，以及用于声明无线电设备符合性的协调标准或其他技术规范的变更，均应得到充分考虑。

When deemed appropriate with regard to the risks presented by radio equipment, manufacturers shall, to protect the health and safety of end-users, carry out sample testing of radio equipment made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming radio equipment and radio equipment recalls, and shall keep distributors informed of any such monitoring. 若考虑到无线电设备所带来的风险，认为采取相关措施是适当的，制造商应为保护终端用户的健康和安全，对投放市场的无线电设备进行抽样测试、开展调查，必要时还应登记投诉情况、不合格无线电设备以及无线电设备召回信息，并将任何此类监控情况告知分销商。

6. Manufacturers shall ensure that radio equipment which they have placed on the market bears a type, batch or serial number or other element allowing its identification, or, where the size or nature of the radio equipment does not allow it, that the required information is provided on the packaging, or in a document accompanying the radio equipment. 6. 制造商应确保其投放市场的无线电设备标有型号、批次或序列号，或其他可用于识别的要素；若因无线电设备的尺寸或性质无法标注，则应在包装上或随附文件中提供所需信息。

7. Manufacturers shall indicate on the radio equipment their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where the size or nature of radio equipment does not allow it, on its packaging, or in a document accompanying the radio equipment. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by end-users and market surveillance authorities. 7. 制造商应在无线电设备上标明其名称、已注册的商号或注册商标，以及可联系到他们的邮政地址；若因无线电设备的尺寸或性质不允许，则应在其包装上或随附文件中标明。该地址应指向一个可联系到制造商的单一地点。联系方式应以终端用户和市场监管机构易于理解的语言呈现。

8. Manufacturers shall ensure that the radio equipment is accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. Instructions shall include the information required to use radio equipment in accordance with its intended use. Such information shall include, where applicable, a description of accessories and components, including software, which allow the radio equipment to operate as intended. Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible. 8. 制造商应确保无线电设备随附的说明和安全信息所使用的语言，是相关成员国确定的、消费者及其他最终用户易于理解的语言。说明应包含按预定用途使用无线电设备所需的信息。

此类信息应在适用情况下,包括对使无线电设备能按预定方式运行的配件和组件(包括软件)的描述。上述说明、安全信息以及任何标签均应清晰、易懂且明了。

The following information shall also be included in the case of radio equipment intentionally emitting radio waves:对于有意发射无线电波的无线电设备,还应包含以下信息:

(a) (a) frequency band(s) in which the radio equipment operates;无线电设备工作的频段;

(b) maximum radio-frequency power transmitted in the frequency band(s) in which the radio equipment operates.无线电设备工作的频段内发射的最大射频功率。

9. Manufacturers shall ensure that each item of radio equipment is accompanied by a copy of the EU declaration of conformity or by a simplified EU declaration of conformity. Where a simplified EU declaration of conformity is provided, it shall contain the exact internet address where the full text of the EU declaration of conformity can be obtained.9. 制造商应确保每件无线电设备均附有欧盟合格声明副本或简化版欧盟合格声明。若提供简化版欧盟合格声明,则应包含可获取欧盟合格声明全文的确切互联网地址。

10. In cases of restrictions on putting into service or of requirements for authorisation of use, information available on the packaging shall allow the identification of the Member States or the geographical area within a Member State where restrictions on putting into service or requirements for authorisation of use exist. Such information shall be completed in the instructions accompanying the radio equipment. The Commission may adopt implementing acts specifying how to present that information. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 45(2).10. 在对投入使用实施限制或要求获得使用授权的情况下,包装上的可用信息应能识别出存在投入使用限制或使用授权要求的成员国或成员国内的地理区域。此类信息应在无线电设备随附的说明书中补充完整。委员会可通过实施法案,具体规定该信息的呈现方式。这些实施法案应根据第45条第(2)款所述的咨询程序通过。

11. Manufacturers who consider or have reason to believe that radio equipment which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that radio equipment into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the radio equipment presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the radio equipment available on the market to that effect, giving details, in particular, of the non-compliance, of any corrective measures taken and of the results thereof.11. 制造商如认为或有理由相信其已投放市场的无线电设备不符合本指令,应立即采取必要的纠正措施,使该无线电设备符合要求,或在适当情况下将其撤回或召回。此外,若该无线电设备存在风险,制造商应立即将此情况通知其已将该无线电设备投放市场的成员国的主管国家当局,并特别详细说明不符合项、已采取的任何纠正措施及其结果。

12. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic

form necessary to demonstrate the conformity of the radio equipment with this Directive, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by radio equipment which they have placed on the market.12. 制造商应在国家主管部门提出合理要求后，以该部门易于理解的语言，向其提供证明无线电设备符合本指令所需的所有纸质或电子形式的信息和文件。应该部门的要求，制造商还应就为消除其投放市场的无线电设备所带来的风险而采取的任何行动进行合作。

Article 11 第11条

Authorised representatives 授权代表

1. A manufacturer may, by a written mandate, appoint an authorised representative.1. 制造商可通过书面授权委托一名授权代表。

The obligations laid down in Article 10(1) and the obligation to draw up technical documentation laid down in Article 10(3) shall not form part of the authorised representative's mandate.第10条第(1)款规定的义务以及第10条第(3)款规定的编制技术文件的义务，不应构成授权代表职权范围的一部分。

2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:2. 授权代表应履行从制造商处获得的授权中规定的任务。该授权应至少允许授权代表从事以下工作：

(a) (a) keep the EU declaration of conformity and the technical documentation at the disposal of national market surveillance authorities for 10 years after the radio equipment has been placed on the market;在无线电设备投放市场后，应将欧盟合格声明和技术文件保存10年，供国家市场监督管理总局查阅；

(b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of radio equipment;应主管国家机关的合理请求，向该机关提供证明无线电设备合规所需的全部信息和文件；

(c) (c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by radio equipment covered by the authorised representative's mandate.应国家主管部门的要求，配合其为消除授权代表职责范围内的无线电设备所带来的风险而采取的任何行动。

Article 12 第12条

Obligations of importers 进口商的义务

1. Importers shall place only compliant radio equipment on the market.1. 进口商仅可将合规的无线电设备投放市场。

2. Before placing radio equipment on the market importers shall ensure that the appropriate conformity assessment procedure referred to in Article 17 has been

carried out by the manufacturer and that the radio equipment is so constructed that it can be operated in at least one Member State without infringing applicable requirements on the use of radio spectrum. They shall ensure that the manufacturer has drawn up the technical documentation, that the radio equipment bears the CE marking and is accompanied by the information and documents referred to in Article 10(8), (9) and (10), and that the manufacturer has complied with the requirements set out in Article 10(6) and (7).2. 在将无线电设备投放市场前，进口商应确保制造商已执行第 17 条所述的适当合格评定程序，且该无线电设备的构造使其至少能在一个成员国境内运行，同时不违反有关无线电频谱使用的适用要求。进口商还应确保制造商已编制技术文件，无线电设备带有 CE 标志，并附有第 10 条第（8）、（9）和（10）款所述的信息和文件，且制造商已遵守第 10 条第（6）和（7）款规定的要求。

Where an importer considers or has reason to believe that radio equipment is not in conformity with the essential requirements set out in Article 3, he shall not place the radio equipment on the market until it has been brought into conformity. Furthermore, where the radio equipment presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.如果进口商认为或有理由相信无线电设备不符合第 3 条规定的基本要求，则在该设备符合要求之前，不得将其投放市场。此外，若无线电设备存在风险，进口商应将此情况通知制造商和市场监管机构。

3. Importers shall indicate on the radio equipment their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the radio equipment. This includes cases where the size of radio equipment does not allow it, or where importers would have to open the packaging in order to indicate their name and address on the radio equipment. The contact details shall be in a language easily understood by end-users and market surveillance authorities.3. 进口商应在无线电设备上标明其名称、已注册的商号或注册商标，以及可联系到他们的邮政地址；若无法在设备上标明，则应在其包装上或随附无线电设备的文件中标明。这包括无线电设备尺寸不允许标明信息，或进口商为在设备上标明其名称和地址而必须打开包装的情况。联系方式应以终端用户和市场监管机构易于理解的语言呈现。

4. Importers shall ensure that the radio equipment is accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.4. 进口商应确保无线电设备随附的说明和安全信息所使用的语言，是相关成员国规定的、能被消费者和其他最终用户轻易理解的语言。

5. Importers shall ensure that, while radio equipment is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Article 3.5. 进口商应确保，在其负责无线电设备期间，设备的储存或运输条件不会影响其符合第 3 条规定的基本要求。

6. When deemed appropriate with regard to the risks presented by radio equipment, importers shall, to protect the health and safety of end-users, carry out sample testing

of radio equipment made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming radio equipment and radio equipment recalls, and shall keep distributors informed of any such monitoring.6. 当考虑到无线电设备带来的风险认为适当的情况下，进口商应为保护终端用户的健康和安全，对投放市场的无线电设备进行抽样测试、调查，必要时还应保留投诉、不合格无线电设备及无线电设备召回的记录，并应将任何此类监控情况告知经销商。

7. Importers who consider or have reason to believe that radio equipment which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that radio equipment into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the radio equipment presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the radio equipment available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.7. 进口商如认为或有理由相信其投放市场的无线电设备不符合本指令，应立即采取必要的纠正措施，使该无线电设备符合要求，或在适当情况下将其撤回或召回。此外，若该无线电设备存在风险，进口商应立即将此情况通知其已投放该无线电设备的成员国的主管国家当局，并详细说明不符合项及所采取的任何纠正措施。

8. Importers shall, for 10 years after the radio equipment has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.8. 进口商应在无线电设备投放市场后的10年内，保留一份欧盟符合性声明，供市场监督机构查阅，并确保应要求能向这些机构提供技术文件。

9. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of radio equipment in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by radio equipment which they have placed on the market.9. 进口商应在国家主管部门提出合理要求后，以该部门易于理解的语言，向其提供证明无线电设备合规所需的所有纸质或电子形式的信息和文件。应该部门的要求，进口商还应配合其为消除已投放市场的无线电设备所带来的风险而采取的任何行动。

Article 13 第13条

Obligations of distributors 经销商的义务

1. When making radio equipment available on the market distributors shall act with due care in relation to the requirements of this Directive.1. 当使无线电设备上市时，经销商应谨慎遵守本指令的要求。

2. Before making radio equipment available on the market distributors shall verify that the radio equipment bears the CE marking, that it is accompanied by the documents required by this Directive and by the instructions and safety information in

a language which can be easily understood by consumers and other end-users in the Member State in which the radio equipment is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 10(2) and (6) to (10) and Article 12(3) respectively. 2. 在将无线电设备投放市场前，经销商应确认该无线电设备带有 CE 标志，随附本指令要求的文件以及使用说明和安全信息，且这些说明和信息所用语言应能被拟投放该无线电设备的成员国的消费者及其他终端用户轻易理解，同时确认制造商和进口商已分别遵守第 10 条第（2）款和第（6）至（10）款以及第 12 条第（3）款规定的要求。

Where a distributor considers or has reason to believe that radio equipment is not in conformity with the essential requirements set out in Article 3, he shall not make the radio equipment available on the market until it has been brought into conformity. Furthermore, where the radio equipment presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities. 如果经销商认为或有理由相信无线电设备不符合第 3 条规定的基本要求，则在该设备符合要求之前，不得将其投放市场。此外，若无线电设备存在风险，经销商应将此情况通知制造商或进口商，并同时告知市场监督机构。

3. Distributors shall ensure that, while radio equipment is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Article 3.3. 经销商应确保，在无线电设备由其负责期间，其储存或运输条件不会影响设备对第 3 条所述基本要求的符合性。

4. Distributors who consider or have reason to believe that radio equipment which they have made available on the market is not in conformity with this Directive shall make sure that the corrective measures necessary to bring that radio equipment into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the radio equipment presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the radio equipment available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken. 4. 经销商如认为或有理由相信其投放市场的无线电设备不符合本指令，应确保采取必要的纠正措施，使该无线电设备符合要求，或在适当情况下将其撤回或召回。此外，若该无线电设备存在风险，经销商应立即将此情况通知其投放该无线电设备的成员国的主管国家当局，并详细说明不符合项及所采取的任何纠正措施。

5. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of radio equipment. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by radio equipment which they have made available on the market. 5. 经销商应根据国家主管部门的合理要求，以纸质或电子形式向其提供证明无线电设备合规性所需的所有信息和文件。应该部门的要求，经销商还应配合其为消除已投放市场的无线电设备所带来的风险而采取的任何行动。

Cases in which obligations of manufacturers apply to importers and distributors **制造商义务适用于进口商和分销商的情形**

An importer or distributor shall be considered a manufacturer for the purposes of this Directive and he shall be subject to the obligations of the manufacturer under Article 10, where he places radio equipment on the market under his name or trade mark or modifies radio equipment already placed on the market in such a way that compliance with this Directive may be affected.在本指令中，若进口商或分销商以自己的名义或商标将无线电设备投放市场，或者对已投放市场的无线电设备进行修改，且该修改可能影响对本指令的合规性，则该进口商或分销商应被视为制造商，并承担第 10 条规定的制造商义务。

Article 15 第 15 条

Identification of economic operators 经济运营商的识别

Economic operators shall, on request, identify the following to the market surveillance authorities:经济经营者应根据要求，向市场监督机构指明以下主体：

- (a) (a) any economic operator who has supplied them with radio equipment;任何向其供应无线电设备的经济运营商；
- (b) any economic operator to whom they have supplied radio equipment.他们曾向其供应无线电设备的任何经济运营商。

Economic operators shall be able to present the information referred to in the first paragraph for 10 years after they have been supplied with the radio equipment and for 10 years after they have supplied the radio equipment.经济运营商应当能够在收到无线电设备后 10 年内以及提供无线电设备后 10 年内，提供第一段所述的信息。

CHAPTER III 第三章

CONFORMITY OF RADIO EQUIPMENT 无线电设备的合规性

Article 16 第 16 条

Presumption of conformity of radio equipment 无线电设备的合格推定

Radio equipment which is in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the essential requirements set out in Article 3 covered by those standards or parts thereof.符合协调标准或其部分内容（其参考编号已在《欧盟官方公报》上公布）的无线电设备，应被推定为符合第 3 条中所述、且由这些标准或其部分内容所涵盖的基本要求。

Article 17 第 17 条

Conformity assessment procedures 合格评定程序

1. The manufacturer shall perform a conformity assessment of the radio equipment with a view to meeting the essential requirements set out in Article 3. The conformity assessment shall take into account all intended operating conditions and, for the essential requirement set out in point (a) of Article 3(1), the assessment shall also take into account the reasonably foreseeable conditions. Where the radio equipment is capable of taking different configurations, the conformity assessment shall confirm whether the radio equipment meets the essential requirements set out in Article 3 in all possible configurations.1. 制造商应对无线电设备进行合格评定，以满足第3条规定的基本要求。合格评定应考虑所有预期工作条件，对于第3条第（1）款（a）项规定的基本要求，评定还应考虑合理可预见的条件。如果无线电设备能够采用不同配置，则合格评定应确认该无线电设备在所有可能的配置下是否满足第3条规定的基本要求。

2. Manufacturers shall demonstrate compliance of radio equipment with the essential requirements set out in Article 3(1) using any of the following conformity assessment procedures:2. 制造商应通过以下任何一种合格评定程序，证明无线电设备符合第3条第（1）款规定的基本要求：

- (a) (a) internal production control set out in Annex II;附件 II 规定的内部生产控制；
- (b) EU-type examination that is followed by the conformity to type based on internal production control set out in Annex III;欧盟型式检验，随后是基于附件 III 规定的内部生产控制的型式符合声明；
- (c) (c) conformity based on full quality assurance set out in Annex IV.附件四规定的基于全面质量保证的合格性

3. Where, in assessing the compliance of radio equipment with the essential requirements set out in Article 3(2) and (3), the manufacturer has applied harmonised standards the references of which have been published in the *Official Journal of the European Union*, he shall use any of the following procedures:3. 在评估无线电设备是否符合第3条第（2）款和第（3）款规定的基本要求时，若制造商已采用其引用已在《欧盟官方公报》上公布的协调标准，则应使用以下任一程序：

- (a) (a) internal production control set out in Annex II;附件 II 规定的内部生产控制；
- (b) EU-type examination that is followed by the conformity to type based on internal production control set out in Annex III;欧盟型式检验，随后是基于附件 III 规定的内部生产控制的型式符合性检查；
- (c) (c) conformity based on full quality assurance set out in Annex IV.基于附件四规定的全面质量保证的符合性

4. Where, in assessing the compliance of radio equipment with the essential requirements set out in Article 3(2) and (3), the manufacturer has not applied or has applied only in part harmonised standards the references of which have been published in the *Official Journal of the European Union*, or where such harmonised standards do not exist, radio equipment shall be submitted with regard to those essential requirements to either of the following procedures:4. 在评估无线电设备是否符合第3条第（2）款和第（3）款规定的基本要求时，若制造商未采用或仅部

分采用已在《欧盟官方公报》上公布参考编号的协调标准，或不存在此类协调标准，则该无线电设备应就这些基本要求遵循以下任一程序：

- (a) (a) EU-type examination that is followed by the conformity to type based on internal production control set out in Annex III; 欧盟型式检验，随后是基于附件 III 规定的内部生产控制的型式符合声明；
- (b) conformity based on full quality assurance set out in Annex IV. 基于附件四规定的全面质量保证的符合性

Article 18 第18条

EU declaration of conformity 欧盟符合性声明

1. The EU declaration of conformity shall state that the fulfilment of the essential requirements set out in Article 3 has been demonstrated. 1. 欧盟合格声明应表明，已证明符合第 3 条规定的基本要求。

2. The EU declaration of conformity shall have the model structure set out in Annex VI, shall contain the elements set out in that Annex and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the radio equipment is placed or made available on the market. 2. 欧盟合格声明应采用附件六规定的标准结构，包含该附件所列要素，并且应不断更新。该声明应翻译成无线电设备投放或供应市场所在成员国要求的一种或多种语言。

The simplified EU declaration of conformity referred to in Article 10(9) shall contain the elements set out in Annex VII and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the radio equipment is placed or made available on the market. The full text of the EU declaration of conformity shall be available at the internet address referred to in the simplified EU declaration of conformity, in a language or languages required by the Member State in which the radio equipment is placed or made available on the market. 第 10 条第 9 款所指的简化版欧盟合格声明应包含附件七所列要素，并应不断更新。该声明应翻译成无线电设备投放或供应市场所在成员国要求的一种或多种语言。完整版欧盟合格声明应在简化版欧盟合格声明所提及的互联网地址上提供，并使用无线电设备投放或供应市场所在成员国要求的一种或多种语言。

3. Where radio equipment is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned including their publication references. 3. 当无线电设备需遵守多项要求出具欧盟合格声明的欧盟法规时，应针对所有这些欧盟法规制定一份单一的欧盟合格声明。该声明应包含相关欧盟法规的标识，包括其发布参考信息。

4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the radio equipment with the requirements laid down in this Directive. 4. 制造商通过拟定欧盟合格声明，应承担使无线电设备符合本指令所规定要求的责任。

Article 19 第19条

General principles of the CE marking CE 标志的一般原则

1. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.1. CE 标志应遵循第 765/2008 号法规 (EC) 第 30 条规定的一般原则。
2. On account of the nature of radio equipment, the height of the CE marking affixed to radio equipment may be lower than 5 mm, provided that it remains visible and legible.2. 由于无线电设备的特性, 粘贴在无线电设备上的 CE 标志的高度可以低于 5 毫米, 前提是标志保持清晰可见且易于辨认。

Article 20 第20条

Rules and conditions for affixing the CE marking and the identification number of the notified body 加贴 CE 标志和公告机构识别号的规则和条件

1. The CE marking shall be affixed visibly, legibly and indelibly to the radio equipment or to its data plate, unless that is not possible or not warranted on account of the nature of radio equipment. The CE marking shall also be affixed visibly and legibly to the packaging.1. CE 标志应清晰、易读且不可磨灭地粘贴在无线电设备或其铭牌上, 除非由于无线电设备的性质而无法或无需如此。CE 标志还应清晰、易读地粘贴在包装上。
2. The CE marking shall be affixed before the radio equipment is placed on the market.2. CE 标志应在无线电设备投放市场前粘贴。
3. The CE marking shall be followed by the identification number of the notified body where the conformity assessment procedure set out in Annex IV is applied.3. 若适用附件四规定的合格评定程序, 则 CE 标志后应附有公告机构的识别编号。

The identification number of the notified body shall have the same height as the CE marking.公告机构的识别编号应与 CE 标志具有相同的高度。

The identification number of the notified body shall be affixed by the notified body itself or, under its instructions, by the manufacturer or his authorised representative.公告机构的识别编号应由公告机构自身加盖, 或在其指示下, 由制造商或其授权代表加盖。

4. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.4. 成员国应利用现有机制, 确保 CE 标志管理制度的正确实施, 并在该标志被不当使用时采取适当行动。

Article 21 第21条

Technical documentation 技术文档

1. The technical documentation shall contain all relevant data or details of the means used by the manufacturer to ensure that radio equipment complies with the essential

requirements set out in Article 3. It shall, at least, contain the elements set out in Annex V.1. 技术文档应包含制造商为确保无线电设备符合第 3 条规定的基本要求所采用手段的所有相关数据或细节。其至少应包含附件五所列的要素。

2. The technical documentation shall be drawn up before radio equipment is placed on the market and shall be continuously updated. 技术文档应在无线电设备投放市场前编制，并应不断更新。

3. The technical documentation and correspondence relating to any EU-type examination procedure shall be drawn up in an official language of the Member State in which the notified body is established or in a language acceptable to that body. 任何欧盟型式检验程序相关的技术文件和通信往来，均应以公告机构所在成员国的官方语言或该机构可接受的语言拟定。

4. Where the technical documentation does not comply with paragraphs 1, 2 or 3 of this Article, and in so doing fails to present sufficient relevant data or means used to ensure compliance of radio equipment with the essential requirements set out in Article 3, the market surveillance authority may ask the manufacturer or the importer to have a test performed by a body acceptable to the market surveillance authority at the expense of the manufacturer or the importer within a specified period in order to verify compliance with the essential requirements set out in Article 3.4. 若技术文档不符合本条第 1 款、第 2 款或第 3 款的规定，且因此未能提供足够的相关数据或用于确保无线电设备符合第 3 条所述基本要求的方法，市场监督机构可要求制造商或进口商在指定期限内，由市场监督机构认可的机构进行测试（费用由制造商或进口商承担），以验证其是否符合第 3 条所述的基本要求。

CHAPTER IV 第四章

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES 合格评定机构的通知

Article 22 第 22 条

Notification 公告

Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under this Directive. 成员国应根据本指令授权执行第三方合格评定任务的机构通知委员会和其他成员国。

Article 23 第 23 条

Notifying authorities 通报机构

1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with Article 28.1. 成员国应指定一个通知机构，该机构负责

建立和执行合格评定机构的评估与通知所需程序，以及对被通知机构的监督，包括对第 28 条的遵守情况。

2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.2. 成员国可决定，第 1 款所述的评估和监测应由符合第 765/2008 号条例（EC）含义并依据该条例设立的国家认可机构开展。

3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, that body shall be a legal entity and shall comply *mutatis mutandis* with the requirements laid down in Article 24. In addition it shall have arrangements to cover liabilities arising out of its activities.3. 若通知机构将第 1 款所述的评估、通知或监督工作委托或以其他方式交由非政府实体的机构负责，则该机构必须是法人实体，并应在细节上作必要修改后遵守第 24 条规定的要求。此外，该机构还应制定相关安排，以承担其活动所产生的责任。

4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.4. 通知机构应对第 3 款所述机构执行的任务承担全部责任。

Article 24 第 24 条

Requirements relating to notifying authorities 与通知机构相关的要求

1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.1. 应设立一个通知机构，确保其与合格评定机构之间不存在利益冲突。

2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.2. 通知机构的组织和运作应能保障其活动的客观性和公正性。

3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.3. 通知机构的组织方式应确保，与合格评定机构通知相关的每项决定均由与执行评定的人员不同的合格人员作出。

4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.4. 通知机构不得在商业或竞争基础上提供合格评定机构所从事的任何活动或咨询服务。

5. A notifying authority shall safeguard the confidentiality of the information it obtains.5. 通知机构应对其获取的信息保密。

6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks. 6. 通知机构应配备足够数量的合格人员，以妥善履行其职责。

Article 25 第25条

Information obligation on notifying authorities 通知机构的信息义务

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto. 成员国应向委员会通报其对合格评定机构的评估和通报程序、对已通报机构的监督程序，以及上述程序的任何变更。

The Commission shall make that information publicly available. 委员会应将该信息公之于众。

Article 26 第26条

Requirements relating to notified bodies 与公告机构相关的要求

1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11. 1. 就通知而言，合格评定机构应满足第2至11款规定的要求。

2. A conformity assessment body shall be established under national law of a Member State and have legal personality. 2. 合格评定机构应依据成员国的国内法设立，并具备法人资格。

3. A conformity assessment body shall be a third-party body independent of the organisation or the radio equipment it assesses. 3. 合格评定机构应当是独立于其评定的组织或无线电设备的第三方机构。

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of radio equipment which it assesses may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body. 代表从事无线电设备设计、制造、提供、组装、使用或维护的企业的商业协会或专业联合会所属的机构，若能证明其独立性且不存在任何利益冲突，则可被视为此类机构。

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the radio equipment which they assess, nor the representative of any of those parties. This shall not preclude the use of assessed radio equipment that is necessary for the operations of the conformity assessment body or the use of such radio equipment for personal purposes. 4. 合格评定机构、其最高管理层以及负责执行合格评定任务的人员，不得是其评定的无线电设备的设计方、制造方、供应方、安装方、采购方、拥有方、使用方或维护方，也不得是上述任何一方的代表。但这并不妨碍合格评定机构为

开展业务而使用经评定的无线电设备，也不妨碍出于个人目的使用此类无线电设备。

A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of that radio equipment, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.合格评定机构、其最高管理层以及负责执行合格评定任务的人员不得直接参与相关无线电设备的设计、制造或建造、营销、安装、使用或维护，也不得代表从事这些活动的各方。他们不得参与任何可能与其在已获认可的合格评定活动中应有的判断独立性或公正性相冲突的活动。这一点尤其适用于咨询服务。

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.合格评定机构应确保其子公司或分包商的活动不会影响其合格评定活动的保密性、客观性或公正性。

5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.5. 合格评定机构及其人员应秉持最高程度的职业诚信，具备特定领域必要的技术能力开展合格评定活动，且应不受任何可能影响其判断或合格评定活动结果的压力和利诱（尤其是经济方面的），特别是在涉及与这些活动结果存在利益关系的个人或群体时。

6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annexes III and IV in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.6. 合格评定机构应能够执行附件 III 和附件 IV 所规定的、与其被通报相关的所有合格评定任务，无论这些任务是由该合格评定机构自行执行，还是由其他机构代表其并在其责任范围内执行。

At all times and for each conformity assessment procedure and each kind or category of radio equipment in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:在任何时候，对于其已获通知的每项合格评定程序以及每类或每类相关无线电设备，合格评定机构都必须拥有必要的：

(a) (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;具备技术知识以及足够且适当经验来执行合格评定任务的人员；

(b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a

notified body and other activities;关于执行合格评定所依据的程序描述,确保这些程序的透明度和可重复性。它应制定适当的政策和程序,以区分其作为公告机构执行的任务和其他活动;

- (c) (c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of radio equipment technology in question and the mass or serial nature of the production process.在开展活动时所遵循的程序,应适当考虑企业规模、所属行业、结构、相关无线电设备技术的复杂程度以及生产过程的批量或 serial 性质。

A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner.合格评定机构应具备以适当方式执行与合格评定活动相关的技术和行政任务所必需的手段。

7. The personnel responsible for carrying out conformity assessment tasks shall have the following:7. 负责执行合格评定任务的人员应具备以下条件:

- (a) (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;涵盖与合格评定机构已获通报相关的所有合格评定活动的完善的技术和职业培训;
- (b)satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;充分了解其执行的评估要求,并拥有执行这些评估的足够权限;
- (c) (c) appropriate knowledge and understanding of the essential requirements set out in Article 3, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation and of national legislation;对第 3 条规定的基本要求、适用的协调标准以及欧盟协调立法和国家立法的相关规定的适当了解和理解;
- (d) (d) the ability to draw up EU-type examination certificates or quality system approvals, records and reports demonstrating that assessments have been carried out.制定欧盟型检验证书或质量体系批准文件、记录和报告的能力,这些文件需能证明已开展评估工作。

8. The impartiality of the conformity assessment bodies, their top level management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.8. 合格评定机构、其高层管理人员以及负责执行合格评定任务的人员的公正性应得到保证。

The remuneration of the top level management and personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.合格评定机构中负责执行合格评定任务的高层管理人员和人员的薪酬,不得取决于所执行的评定数量或这些评定的结果。

9. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is

directly responsible for the conformity assessment.9. 合格评定机构应购买责任保险，除非根据国家法律由国家承担责任，或者成员国自身直接负责合格评定。

10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Annexes III and IV or any provision of national law giving effect to them, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.10. 合格评定机构的人员应对在执行附件三、附件四规定的任务或任何实施这些附件的国家法律条款过程中获得的所有信息遵守职业保密义务，但向其开展活动所在成员国的主管当局提供信息的情况除外。知识产权应受到保护。

11. Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities, the regulatory activities in the area of radio equipment and frequency planning, and the activities of the notified body coordination group established under the relevant Union harmonisation legislation and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.11. 合格评定机构应当参与相关标准化活动、无线电设备和频率规划领域的监管活动以及根据相关欧盟协调立法设立的公告机构协调组的活动，或者确保其负责执行合格评定任务的人员了解这些活动，并应当将该协调组的工作成果所产生的行政决定和文件作为一般指导加以应用。

Article 27 第27条

Presumption of conformity of notified bodies 公告机构的合格推定

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* it shall be presumed to comply with the requirements set out in Article 26 in so far as the applicable harmonised standards cover those requirements.如果一家合格评定机构证明其符合相关协调标准或其部分内容中规定的标准，且这些标准或其部分内容的引用已在《欧盟官方公报》上公布，则在适用的协调标准涵盖第26条规定的要求的范围内，应推定该机构符合这些要求。

Article 28 第28条

Subsidiaries of and subcontracting by notified bodies 公告机构的子公司及分包

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 26 and shall inform the notifying authority accordingly.1. 当公告机构将与合格评定相关的特定任务分包出去，或借助子公司完成时，其应确保分包商或子公司符合第26条规定的要求，并相应地通知公告机构。

2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.2. 公告机构应对分包商或子公司（无论其设立地点在哪里）所执行的任务承担全部责任。

3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.3. 只有在获得客户同意的情况下，活动才可进行分包或由子公司实施。

4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Annexes III and IV.4. 公告机构应将分包商或子公司资质评估相关的文件，以及其根据附件三与附件四所开展工作的相关文件，留存备查，供通知机构查阅。

Article 29 第 29 条

Application for notification 通知申请

1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.1. 合格评定机构应向其所在成员国的通知机构提交通知申请。

2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the radio equipment for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 26.2. 通知申请应随附一份关于合格评定活动、合格评定模块（一个或多个）以及该机构声称具备资质的无线电设备的说明，若存在由国家认可机构颁发的认可证书，还应随附该证书，以证明该合格评定机构符合第 26 条规定的要求。

3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 26.3. 若相关合格评定机构无法提供认可证书，则应向通知机构提供核实、认可和定期监督其是否符合第 26 条规定要求所必需的所有书面证据。

Article 30 第 30 条

Notification procedure 通知程序

1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 26.1. 通知机构只能通知那些满足第 26 条规定要求的合格评定机构。

2. They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.2. 它们应使用由委员会开发和管理的电子通知工具通知委员会和其他成员国。

3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and the radio equipment concerned and the relevant attestation of competence. 3. 通知应包含合格评定活动的全部细节、相关的一个或多个合格评定模块、涉及的无线电设备以及相关的能力证明。

4. Where a notification is not based on an accreditation certificate as referred to in Article 29(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 26. 4. 若通知并非基于第 29 条第 (2) 款所述的认可证书, 通知机构应向委员会及其他成员国提供书面证据, 以证明合格评定机构的能力, 以及为确保该机构得到定期监督并持续满足第 26 条规定的要求而制定的各项安排。

5. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used. 5. 相关机构只有在以下情况下方可开展公告机构的活动: 若使用了认证证书, 则在通知发出后两周内, 委员会或其他成员国未提出异议; 若未使用认证, 则在通知发出后两个月内, 委员会或其他成员国未提出异议。

Only such a body shall be considered a notified body for the purposes of this Directive. 就本指令而言, 只有此类机构才应被视为公告机构。

6. The notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification. 6. 通知机构应将通知后续发生的任何相关变更通知委员会及其他成员国。

Article 31 第 31 条

Identification numbers and lists of notified bodies 公告机构的识别编号和名单

1. The Commission shall assign an identification number to a notified body. 1. 委员会应向被通知机构分配一个识别编号。

It shall assign a single such number even where the body is notified under several Union acts. 即使该机构是根据多项欧盟法规被通知的, 委员会也应仅为其分配一个此类编号。

2. The Commission shall make publicly available the list of the bodies notified under this Directive, including the identification numbers that have been assigned to them and the activities for which they have been notified. 2. 委员会应公开根据本指令通报的机构名单, 包括为这些机构分配的识别号码以及其通报所涉及的活动。

The Commission shall ensure that the list is kept up to date. 委员会应确保该清单保持最新。

Article 32 第 32 条

Changes to notifications 通知的变更

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 26, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.1. 若通知机构确定或获悉被通知机构不再符合第 26 条规定的要求，或未能履行其义务，通知机构应根据不符合这些要求或未履行这些义务的严重程度，酌情限制、暂停或撤销通知。通知机构应立即相应地通知委员会和其他成员国。
2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.2. 若通知被限制、暂停或撤回，或被通知机构已停止其活动，通知成员国应采取适当措施，确保该机构的档案要么由另一被通知机构处理，要么应负责的通知机构和市场监管机构的要求随时可供其使用。

Article 33 第 33 条

Challenge of the competence of notified bodies 对公告机构权限的质疑

1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.1. 对于任何委员会有理由怀疑，或经人提醒其注意到某一公告机构的能力，或该公告机构是否持续满足其应遵守的要求和承担的责任的情况，委员会均应展开调查。
2. The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the notified body concerned.2. 应要求，发出通知的成员国应向委员会提供与通知依据或相关被通知机构权限维持有关的所有信息。
3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.3. 委员会应确保在调查过程中获得的所有敏感信息都得到保密处理。
4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall adopt an implementing act requesting the notifying Member State to take the necessary corrective measures, including withdrawal of notification if necessary.4. 当委员会确定某一被通知机构不符合或不再符合其被通知的要求时，应通过一项实施法案，要求通知成员国采取必要的纠正措施，必要时包括撤销通知。

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 45(2).该实施法案应根据第 45 条第 (2) 款所述的咨询程序通过。

Article 34 第34条

Operational obligations of notified bodies 公告机构的运营义务

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annexes III and IV.1. 公告机构应按照附件 III 和附件 IV 规定的合格评定程序开展合格评定工作。

2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the radio equipment technology in question and the mass or serial nature of the production process.2. 合格评定应按比例进行, 避免给经济运营商带来不必要的负担。合格评定机构在开展活动时, 应适当考虑企业规模、所属行业、结构、相关无线电设备技术的复杂程度以及生产过程的批量或 serial 性质。

In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the radio equipment with this Directive. 尽管如此, 在这样做时, 他们仍应尊重为使无线电设备符合本指令所必需的严谨程度和保护水平。

3. Where a notified body finds that the essential requirements set out in Article 3 or corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue an EU-type examination certificate or a quality system approval.3. 若公告机构发现制造商未满足第 3 条规定的基本要求或相应的协调标准或其他技术规范, 该机构应要求制造商采取适当的纠正措施, 且不得签发欧盟型式检验证书或质量体系批准书。

4. Where, in the course of the monitoring of conformity following the issue of an EU-type examination certificate or a quality system approval, a notified body finds that radio equipment no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the EU-type examination certificate or the quality system approval if necessary.4. 在欧盟型式检验证书或质量体系批准颁发后进行合格性监测的过程中, 若公告机构发现无线电设备不再符合要求, 应要求制造商采取适当的纠正措施, 并在必要时暂停或撤销该欧盟型式检验证书或质量体系批准。

5. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any EU-type examination certificates or quality system approvals, as appropriate.5. 若未采取纠正措施或纠正措施未达到预期效果, notified body 应酌情限制、暂停或撤销任何欧盟型式检验证书或质量体系批准。

Article 35 第35条

Appeal against decisions of notified bodies 对公告机构决定的申诉

Member States shall ensure that an appeal procedure against decisions of the notified bodies is available.成员国应确保存在针对公告机构决定的申诉程序。

Article 36 第36条

Information obligation on notified bodies 公告机构的信息义务

1. Notified bodies shall inform the notifying authority of the following:1. 公告机构应将以下事项通知通告机构:

- (a) (a) any refusal, restriction, suspension or withdrawal of an EU-type examination certificate or a quality system approval in accordance with the requirements of Annexes III and IV; 根据附件 III 和 IV 的要求, 任何拒绝、限制、暂停或撤销欧盟型式检验证书或质量体系批准的行为;
- (b) any circumstances affecting the scope of or conditions for notification;任何影响通知范围或通知条件的情况;
- (c) (c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;他们从市场监督机构收到的任何有关合格评定活动的信息请求;
- (d) (d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.应要求, 在其通报范围内开展的合格评定活动以及所开展的任何其他活动, 包括跨境活动和分包活动。

2. Notified bodies shall, in accordance with the requirements of Annexes III and IV, provide the other bodies notified under this Directive carrying out similar conformity assessment activities covering the same categories of radio equipment with relevant information on issues relating to negative and, on request, positive conformity assessment results.2. 公告机构应根据附件三及附件四的要求, 向本指令下被公告且从事涵盖相同类别无线电设备的类似合格评定活动的其他机构, 提供与不合格评定结果相关的信息; 并应要求提供与合格评定结果相关的信息。

3. Notified bodies shall fulfil information obligations under Annexes III and IV.3. 公告机构应履行附件 III 和附件 IV 规定的信息义务。

Article 37 第37条

Exchange of experience 经验交流

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.委员会应组织成员国负责通知政策的国家当局之间的经验交流。

Article 38 第38条

Coordination of notified bodies 公告机构的协调

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Directive are put in place and properly operated in the form of a sectoral group of notified bodies.委员会应确保以指定机构部门小组的形式, 在根据本指令被指定的各机构之间建立并妥善开展适当的协调与合作。

Member States shall ensure that the bodies notified by them participate in the work of that group, directly or by means of designated representatives.成员国应确保其通知的机构直接或通过指定代表参与该小组的工作。

CHAPTER V 第五章

UNION MARKET SURVEILLANCE, CONTROL OF RADIO EQUIPMENT ENTERING THE UNION MARKET AND UNION SAFEGUARD PROCEDURE 欧盟市场监督、进入欧盟市场的无线电设备管控及欧盟保障程序

Article 39 第39条

Union market surveillance and control of radio equipment entering the Union market 欧盟市场监督及对进入欧盟市场的无线电设备的管控

Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to radio equipment.《欧洲共同体第 765/2008 号条例》第 15 条第 3 款以及第 16 条至第 29 条适用于无线电设备。

Article 40 第40条

Procedure for dealing with radio equipment presenting a risk at national level 国家级无线电设备风险处理程序

1. Where the market surveillance authorities of one Member State have sufficient reason to believe that radio equipment covered by this Directive presents a risk to the health or safety of persons or to other aspects of public interest protection covered by this Directive, they shall carry out an evaluation in relation to the radio equipment concerned covering all relevant requirements laid down in this Directive. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose.1. 若某一成员国的市场监督机构有充分理由相信本指令所涵盖的无线电设备对人体健康或安全, 或对本指令所涵盖的其他公共利益保护方面构成风险, 则该机构应对相关无线电设备进行评估, 评估范围包括本指令规定的所有相关要求。相关经济运营商应为此与市场监督机构进行必要的合作。

Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that the radio equipment does not comply with the requirements laid down in this Directive, they shall without delay require the relevant economic operator to take all appropriate corrective actions to bring the radio equipment into compliance with those requirements, to withdraw the radio equipment from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.在第一款所述的评估过程中, 若市场监督机构发现无线电设备不符合本指令规定的要求, 应立即要求相关经济运营商采取

一切适当的纠正措施，使该无线电设备符合这些要求，或将其撤出市场，或在与风险性质相适应的合理期限内按照其规定召回该设备。

The market surveillance authorities shall inform the relevant notified body accordingly. 市场监督机构应相应地通知相关的公告机构。

Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph of this paragraph. 《欧洲共同体条例》（EC）第 765/2008 号第 21 条应适用于本款第二项所指的措施。

2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take. 2. 若市场监管机构认为不合规情况并非仅限于其本国领土，应将评估结果以及要求经济运营商采取的措施通知欧盟委员会和其他成员国。

3. The economic operator shall ensure that all appropriate corrective action is taken in respect of all radio equipment concerned that it has made available on the market throughout the Union. 3. 经济运营商应确保对其在整个欧盟市场上投放的所有相关无线电设备采取一切适当的纠正措施。

4. Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the radio equipment being made available on their national market, to withdraw the radio equipment from that market or to recall it. 4. 若相关经济运营商未在第 1 款第二段所述期限内采取充分的纠正措施，市场监管机构应采取一切适当的临时措施，禁止或限制该无线电设备在其国家市场上流通、将其从市场撤出或予以召回。

The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures. 市场监督机构应立即将这些措施通知委员会和其他成员国。

5. The information referred to in the second subparagraph of paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant radio equipment, the origin of the radio equipment, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either of the following: 5. 第 4 款第二项所指的信息应包括所有可获得的细节，特别是识别不合规无线电设备所需的数据、无线电设备的来源、所指称的不合规性质及涉及的风险、所采取国家措施的性质和持续时间，以及相关经济运营商提出的论据。市场监管机构尤其应指出不合规是否由以下任一原因造成：

(a) (a) failure of the radio equipment to meet the relevant essential requirements set out in Article 3; or 无线电设备未能满足第 3 条规定的相关基本要求；或

(b) shortcomings in the harmonised standards referred to in Article 16 conferring a presumption of conformity. 第 16 条所指的协调标准中存在的、赋予合规推定的缺陷。

6. Member States other than the Member State initiating the procedure under this Article shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the radio equipment concerned, and, in the event of disagreement with the adopted national measure, of their objections. 6. 除根据本条启动程序的成员国之外，其他成员国应立即将其采取的任何措施、掌握的与相关无线电设备不合规情况有关的任何补充信息，以及在对所采取的国家措施有异议时的反对意见，通知委员会和其他成员国。

7. Where, within three months of receipt of the information referred to in the second subparagraph of paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified. 7. 若成员国或委员会在收到第 4 款第二段所述信息后的三个月内，未对某一成员国采取的临时措施提出异议，则该措施应被视为合理。

8. Member States shall ensure that appropriate restrictive measures, such as withdrawal of the radio equipment from the market, are taken in respect of the radio equipment concerned without delay. 8. 成员国应确保立即对相关无线电设备采取适当的限制性措施，例如将其撤出市场。

Article 41 第 41 条

Union safeguard procedure 欧盟保障程序

1. Where, on completion of the procedure set out in Article 40(3) and (4), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall adopt an implementing act determining whether the national measure is justified or not. 1. 在完成第 40 条第 (3) 款和第 (4) 款规定的程序后，如对某成员国采取的措施提出异议，或委员会认为某国家措施违反欧盟立法，委员会应立即与各成员国及相关经济经营者进行磋商，并对该国家措施进行评估。基于评估结果，委员会应通过一项实施法案，确定该国家措施是否合理。

The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators. 委员会应将其决定通知所有成员国，并立即将该决定传达给这些成员国以及相关的一个或多个经济运营商。

2. If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant radio equipment is withdrawn or recalled from their market, and shall inform the Commission accordingly. If the

national measure is considered unjustified, the Member State concerned shall withdraw that measure.2. 若该国家措施被认定为合理，所有成员国均应采取必要措施，确保不合格无线电设备从其市场撤出或召回，并相应通知欧盟委员会。若该国家措施被认定为不合理，相关成员国应撤销该措施。

3. Where the national measure is considered justified and the non-compliance of the radio equipment is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 40(5) of this Directive, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.3. 若国家措施被认为具有正当性，且无线电设备不符合要求的原因在于本指令第 40 条第(5)款 (b) 项所述的协调标准存在缺陷，则委员会应适用《欧盟条例》第 1025/2012 号第 11 条规定的程序。

Article 42 第 42 条

Compliant radio equipment which presents a risk 存在风险的合规无线电设备

1. Where, having carried out an evaluation under Article 40(1), a Member State finds that although radio equipment is in compliance with this Directive, it presents a risk to the health or safety of persons or to other aspects of public interest protection covered by this Directive, it shall require the relevant economic operator to take all appropriate measures to ensure that the radio equipment concerned, when placed on the market, no longer presents that risk, to withdraw the radio equipment from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.1. 若成员国根据第 40 条第 (1) 款进行评估后发现，尽管无线电设备符合本指令，但仍对人员健康或安全，或本指令所涵盖的公共利益保护的其他方面构成风险，则该成员国应要求相关经济运营商采取一切适当措施，确保相关无线电设备在投放市场时不再存在该风险，并按其规定，在与风险性质相适应的合理期限内将该无线电设备撤出市场或召回。

2. The economic operator shall ensure that corrective action is taken in respect of all the radio equipment concerned that he has made available on the market throughout the Union.2. 经济运营商应确保对其在整个欧盟市场上投放的所有相关无线电设备采取纠正措施。

3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the radio equipment concerned, the origin and the supply chain of radio equipment, the nature of the risk involved and the nature and duration of the national measures taken.3. 成员国应立即通知委员会和其他成员国。该信息应包括所有可获得的细节，特别是识别相关无线电设备所需的数据、无线电设备的来源和供应链、所涉及风险的性质以及所采取国家措施的性质和持续时间。

4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide by means of implementing acts whether the national measure is justified or not

and, where necessary, propose appropriate measures.4. 委员会应立即与成员国以及相关的一个或多个经济运营商进行磋商，并对所采取的国家措施进行评估。根据评估结果，委员会应通过实施法案决定国家措施是否合理，并在必要时提出适当的措施。

The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the examination procedure referred to in Article 45(3). 本款第一项所指的实施法案应依照第 45 条第（3）款所述的审查程序通过。

On duly justified imperative grounds of urgency relating to the protection of health and safety of persons, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 45(4). 基于保护人员健康和安全的正当且紧急的必要理由，委员会应依照第 45 条第（4）款所述程序，通过可立即适用的实施法案。

5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.5. 委员会应将其决定送达所有成员国，并立即向它们以及相关的一个或多个经济运营商通报该决定。

Article 43 第 43 条

Formal non-compliance 正式不合规

1. Without prejudice to Article 40, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:1. 在不损害第 40 条的前提下，若某成员国作出以下任一认定，应要求相关经济经营者终止相关不合规行为：

(a) (a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 20 of this Directive; 加贴 CE 标志的行为违反了第 765/2008 号法规（EC）第 30 条或本指令第 20 条的规定；

(b) the CE marking has not been affixed; 未加贴 CE 标志；

(c) (c) the identification number of the notified body, where the conformity assessment procedure set out in Annex IV is applied, has been affixed in violation of Article 20 or has not been affixed; 在适用附件四规定的合格评定程序的情况下，公告机构的识别编号被违规粘贴（违反第 20 条）或未被粘贴；

(d) (d) the EU declaration of conformity has not been drawn up; 未拟定欧盟合格声明；

(e) the EU declaration of conformity has not been drawn up correctly; 欧盟符合性声明未正确拟定；

(f) technical documentation is either not available or not complete; 技术文件要么无法获取，要么不完整；

(g) (g) the information referred to in Article 10(6) or (7) or Article 12(3) is absent, false or incomplete; 第 10 条第 6 款或第 7 款或第 12 条第 3 款所述信息缺失、虚假或不完整；

(h) (h) information on the intended use of radio equipment, the EU declaration of

备支持某些功能，conformity or usage restrictions as set out in Article 10(8), (9) and (10) does 以方便残障用户使用not accompany the radio equipment;关于无线电设备预期用途的信息、欧用；
盟合格声明或第 10 条第（8）、（9）和（10）款规定的使用限制未随无线电设备一同提供；

(i) (i) 无线电设备支持某些功能，以确保requirements on identification of economic 只有在已证明无线电设备与软件的组合符合operators set out in Article 15 are not fulfilled;第要求的条件下，才能将软件加载到该无线电15 条规定的对经济运营商的识别要求未得到满设备中。
足；

(j) (j) Article 5 is not complied with. 第 5 条未得到遵守。

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit corresponding radio equipment being made available on the market or ensure that it is withdrawn or recalled from the market.2. 若第 1 款所述的不合规情况持续存在，相关成员国应采取一切适当措施，限制或禁止相关无线电设备投放市场，或确保其从市场上撤回或召回。

CHAPTER VI 第六章

DELEGATED ACTS AND IMPLEMENTING ACTS AND THE COMMITTEE 授权法案、实施法案及委员会

Article 44 第 44 条

Exercise of the delegation 授权的行使

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.1. 根据本条规定的条件，授权委员会采取 delegated acts 的权力。

2. The power to adopt delegated acts referred to in the second subparagraph of Articles 3(3), 4(2) and 5(2) shall be conferred on the Commission for a period of five years from 11 June 2014. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.2. 第 3 条第 3 款第二项、第 4 条第 2 款和第 5 条第 2 款所述的通过授权法案的权力，应自 2014 年 6 月 11 日起授予委员会，期限为五年。委员会应在五年期限结束前至少九个月就权力下放事宜起草一份报告。除非欧洲议会或理事会在每段期限结束前至少三个月反对延长，否则该授权应自动延长相同的期限。

3. The delegation of power referred to in the second subparagraph of Articles 3(3), 4(2) and 5(2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall

not affect the validity of any delegated acts already in force.3. 第3条第3款第二项、第4条第2款和第5条第2款所述的权力委托,可由欧洲议会或理事会随时撤销。撤销决定应终止该决定中所指明的权力委托。该决定在《欧盟官方公报》上公布后的次日生效,或在决定中规定的更晚日期生效。此撤销不影响任何已生效的授权法案的效力。

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.4. 委员会一旦通过一项授权法案,应立即将其同时通知欧洲议会和理事会。

5. A delegated act adopted pursuant to the second subparagraph of Articles 3(3), 4(2) and 5(2) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.5. 根据第3条第3款第二项、第4条第2款和第5条第2款通过的授权法案,只有在该法案通知欧洲议会和理事会后的两个月内,欧洲议会或理事会均未表示反对,或者在该期限届满前,欧洲议会和理事会均已通知委员会它们不反对的情况下,方可生效。经欧洲议会或理事会提议,该期限可延长两个月。

Article 45 第45条

Committee procedure 委员会程序

1. The Commission shall be assisted by the Telecommunication Conformity Assessment and Market Surveillance Committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.1. 委员会将由电信合格评定和市场监督委员会提供协助。该委员会是符合(欧盟)第182/2011号条例定义的委员会。

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.2. 凡提及本款时,应适用《欧盟条例》第182/2011号第4条。

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.3. 凡提及本款时,应适用《欧盟条例》(第182/2011号)第5条。

4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.4. 凡提及本款时,应适用《欧盟条例》(EU)第182/2011号第8条以及该条例第5条的相关规定。

5. The committee shall be consulted by the Commission on any matter for which consultation of sectoral experts is required by Regulation (EU) No 1025/2012 or by any other Union legislation.5. 对于《欧盟条例》第1025/2012号或任何其他欧盟立法要求咨询行业专家的任何事项,委员会应咨询该委员会。

The committee may furthermore examine any other matter concerning the application of this Directive raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.此外，委员会可根据其议事规则，审查由主席或成员国代表提出的与本指令适用相关的任何其他事项。

CHAPTER VII 第七章

FINAL AND TRANSITIONAL PROVISIONS 最终条款及过渡条款

Article 46 第46条

Penalties 处罚

Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements.成员国应制定关于经济运营商违反根据本指令通过的国内法规定的处罚规则，并应采取一切必要措施确保这些规则得到执行。此类规则可包括对严重违规行为的刑事处罚。

The penalties provided for shall be effective, proportionate and dissuasive.所规定的处罚应当有效、适当且具有威慑力。

Article 47 第47条

Review and reporting 审查与报告

1. Member States shall submit to the Commission regular reports on the application of this Directive by 12 June 2017 and at least every two years thereafter. The reports shall contain a presentation of the market surveillance activities performed by the Member States and provide information on whether and to what extent compliance with the requirements of this Directive has been attained, including in particular requirements on identification of economic operators.1. 成员国应于2017年6月12日前向委员会提交关于本指令实施情况的定期报告，此后至少每两年提交一次。报告应说明成员国开展的市场监督活动，并提供关于是否及在何种程度上达到本指令要求（特别是关于经济运营商识别的要求）的信息。

2. The Commission shall review the operation of this Directive and report thereon to the European Parliament and to the Council, by 12 June 2018 and every five years thereafter. The report shall cover progress on drawing up the relevant standards, as well as any problems that have arisen in the course of implementation. The report shall also outline the activities of the Telecommunication Conformity Assessment and Market Surveillance Committee, assess progress in achieving an open competitive market for radio equipment at Union level and examine how the regulatory framework for the making available on the market and putting into service of radio equipment should be developed in order to achieve the following:2. 委员会应审查本指令的实施情况，并于2018年6月12日前及其后每五年向欧洲议会和理事会提交相关报告。报告应涵盖相关标准制定的进展，以及在实施过程中出现的任何问

题。报告还应概述电信合格评定和市场监管委员会的活动，评估在欧盟层面建立开放竞争的无线电设备市场的进展，并探讨应如何完善无线电设备投放市场和投入使用的监管框架，以实现以下目标：

- (a) (a) ensure that a coherent system is achieved at Union level for all radio equipment; 确保在联盟层面为所有无线电设备建立一个连贯的体系；
- (b) allow for convergence of the telecommunications, audiovisual and information technology sectors; 为电信、视听和信息技术行业的融合创造条件；
- (c) (c) enable regulatory measures to be harmonised at international level; 使监管措施能够在国际层面得到协调；
- (d) (d) reach a high level of consumer protection; 达到高水平的消费者保护；
- (e) ensure that portable radio equipment interworks with accessories, in particular with common chargers; 确保便携式无线电设备与配件（特别是通用充电器）能够互通工作；
- (f) where radio equipment is fitted with an integral screen, allow the display of the required information on the integral screen. 如果无线电设备配备了内置屏幕，则允许在该内置屏幕上显示所需信息。

Article 48 第48条

Transitional provisions 过渡性条款

Member States shall not impede, for the aspects covered by this Directive, the making available on the market or putting into service of radio equipment covered by this Directive which is in conformity with the relevant Union harmonisation legislation applicable before 13 June 2016 and which was placed on the market before 13 June 2017. 对于本指令所涵盖的方面，成员国不得阻碍符合2016年6月13日之前适用的相关欧盟协调立法且于2017年6月13日之前投放市场的本指令所涉无线电设备在市场上供应或投入使用。

Article 49 第49条

Transposition 转换

1. Member States shall adopt and publish, by 12 June 2016, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate the text of those measures to the Commission. 1. 成员国应在2016年6月12日前通过并公布为遵守本指令所必需的法律、法规和行政规定。它们应立即将这些措施的文本通报给委员会。

They shall apply those measures from 13 June 2016. 它们应自2016年6月13日起实施这些措施。

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to the Directive repealed by this Directive

shall be construed as references to this Directive. Member States shall determine how such reference is to be made and how that statement is to be formulated. 成员国在采取这些措施时，应在措施中提及本指令，或在其官方公布时附上该提及内容。成员国还应作出声明，表明现行法律、法规和行政规定中对被本指令废止的指令的引用，应视为对本指令的引用。成员国应确定如何进行此类提及以及如何拟定该声明。

2. Member States shall communicate to the Commission the texts of the main provisions of national law which they adopt in the field covered by this Directive. 成员国应向委员会通报其在本指令所涵盖领域内通过的国内法主要条款文本。

Article 50 第50条

Repeal 废除

Directive 1999/5/EC is repealed with effect from 13 June 2016. 1999/5/EC 号指令自2016年6月13日起废止。

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex VIII. 凡提及已废除的指令，均应视为提及本指令，并应依照附件八中的对照表进行解读。

Article 51 第51条

Entry into force 生效

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*. 本指令应在《欧盟官方公报》上公布后的第二十天生效。

Article 52 第52条

Addressees 适用对象

This Directive is addressed to the Member States. 本指令针对各成员国。

Done at Strasbourg, 16 April 2014. 2014年4月16日于斯特拉斯堡签署。

*For the European
Parliament 欧洲议
会*（注：结合语
境为指令末尾的
署名部分，“*For
the European
Parliament*”在此
处表示该指令由
欧洲议会发出，故
翻译为“欧洲议

会”，符合官方文件的表述习惯。)

The President 主席

M. SCHULZ M.舒尔茨

For the Council 致理事会

The President 主席

D.
KOURKOULAS
D. 库尔库拉斯

(¹) OJ C 133, 9.5.2013, p. 58.(1) 《欧盟公报》(C系列)第133期, 2013年5月9日, 第58页。

(²) Position of the European Parliament of 13 March 2014 (not yet published in the Official Journal) and decision of the Council of 14 April 2014. (2) 欧洲议会2014年3月13日的立场(尚未在《官方公报》上公布)以及理事会2014年4月14日的决定。

(³) Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity (OJ L 91, 7.4.1999, p. 10). (3) 欧洲议会和理事会1999年3月9日关于无线电设备和电信终端设备及其合格性相互认可的第1999/5/EC号指令(《官方公报》L 91, 1999年4月7日, 第10页)。

(⁴) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30). (4) 欧洲议会和理事会2008年7月9日关于制定产品营销相关的认证和市场监督要求并废止第339/93号条例(EEC)的第765/2008号条例(EC)(《官方公报》L 218, 2008年8月13日, 第30页)。

(⁵) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82). (5) 欧洲议会和理事会2008年7月9日关于产品营销共同框架并废止理事会第93/465/EEC号决定的第768/2008/EC号决定(《欧盟公报》L 218, 2008年8月13日, 第82页)。

(⁶) Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (OJ L 96, 29.3.2014, p. 357). (6) 欧洲议会和理事会2014年2月26日关于协调成员国有关在市场上投放设计用于特定电压范围内的电气设备的法律的第2014/35/EU号指令(《欧盟官方公报》L 96号, 2014年3月29日, 第357页)。

(⁷) Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (OJ L 96, 29.3.2014, p. 79). (7) 欧洲议会和理事会2014年2月26日关于协调成员国电磁兼容性相关法律的第2014/30/EU号指令(《官方公报》L 96, 2014年3月29日, 第79页)。

(⁸) Commission Directive 2008/63/EC of 20 June 2008 on competition in the markets in telecommunications terminal equipment (OJ L 162, 21.6.2008, p. 20). (8) 2008年6月20日关于电信终端设备市场竞争的欧盟委员会第2008/63/EC号指令(《欧盟官方公报》L 162, 2008年6月21日, 第20页)。

⁽⁹⁾ Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (OJ L 204, 21.7.1998, p. 37). (9) 欧洲议会和理事会 1998 年 6 月 22 日关于制定技术标准和法规领域以及信息社会服务规则方面的信息提供程序的第 98/34/EC 号指令（《官方公报》L 204 号，1998 年 7 月 21 日，第 37 页）。

⁽¹⁰⁾ Decision No 676/2002/EC of the European Parliament and of the Council of 7 March 2002 on a regulatory framework for radio spectrum policy in the European Community (Radio Spectrum Decision) (OJ L 108, 24.4.2002, p. 1). (10) 欧洲议会和理事会 2002 年 3 月 7 日关于欧洲共同体无线电频谱政策监管框架的第 676/2002/EC 号决定（《无线电频谱决定》）（《官方公报》L 108 号，2002 年 4 月 24 日，第 1 页）。

⁽¹¹⁾ Commission Decision 2007/344/EC of 16 May 2007 on harmonised availability of information regarding spectrum use within the Community (OJ L 129, 17.5.2007, p. 67). (11) 2007 年 5 月 16 日欧盟委员会第 2007/344/EC 号关于在欧共同体内统一提供频谱使用相关信息的决定（《欧盟官方公报》L 129 号，2007 年 5 月 17 日，第 67 页）。

⁽¹²⁾ Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12). (12) 欧洲议会和理事会 2012 年 10 月 25 日关于欧洲标准化的第 1025/2012 号条例（EU），修订理事会第 89/686/EEC 号和第 93/15/EEC 号指令以及欧洲议会和理事会第 94/9/EC 号、第 94/25/EC 号、第 95/16/EC 号、第 97/23/EC 号、第 98/34/EC 号、第 2004/22/EC 号、第 2007/23/EC 号、第 2009/23/EC 号和第 2009/105/EC 号指令，并废止理事会第 87/95/EEC 号决定和欧洲议会与理事会第 1673/2006/EC 号决定（《官方公报》L 316，2012 年 11 月 14 日，第 12 页）。

⁽¹³⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13). (13) 欧洲议会和理事会 2011 年 2 月 16 日第 182/2011 号条例（EU），该条例规定了成员国对委员会行使执行权的控制机制的规则和一般原则（《欧盟官方公报》L 55，2011 年 2 月 28 日，第 13 页）。

⁽¹⁴⁾ OJ C 369, 17.12.2011, p. 14. (14) 《欧盟公报》C 369 号，2011 年 12 月 17 日，第 14 页。

⁽¹⁵⁾ Directive 2002/21/EC of the European Parliament and of the Council of 7 March 2002 on a common regulatory framework for electronic communications networks and services (Framework Directive) (OJ L 108, 24.4.2002, p. 33). (15) 欧洲议会和理事会 2002 年 3 月 7 日关于电子通信网络和服务共同监管框架的第 2002/21/EC 号指令（《框架指令》）（《官方公报》L 108 号，2002 年 4 月 24 日，第 33 页）。

ANNEX I 附件一

EQUIPMENT NOT COVERED BY THIS DIRECTIVE 本指令不涵盖的设备

1.

Radio equipment used by radio amateurs within the meaning of Article 1, definition 56, of the International Telecommunications Union (ITU) Radio Regulations, unless the equipment is made available on the market. 国际电信联盟（ITU）《无线电规则》第 1 条第 56 项定义所指的无线电爱好者使用的无线电设备，但该设备在市场上可购得的情况除外。

The following shall be regarded as not being made available on the market: 以下情形应视为未投放市场:

- (a) (a) radio kits for assembly and use by radio amateurs; 供无线电爱好者组装和使用的无线电套件;
- (b) radio equipment modified by and for the use of radio amateurs; 由无线电爱好者改装并供其使用的无线电设备;
- (c) (c) equipment constructed by individual radio amateurs for experimental and scientific purposes related to amateur radio. 由业余无线电爱好者个人制造、用于与业余无线电相关的实验和科学目的的设备。

2.

Marine equipment falling within the scope of Council Directive 96/98/EC ⁽¹⁾.

2. 属于理事会第 96/98/EC 号指令⁽¹⁾范围内的船用设备。

3.

Airborne products, parts and appliances falling within the scope of Article 3 of Regulation (EC) No 216/2008 of the European Parliament and of the Council ⁽²⁾.

3. 属于欧洲议会和理事会第 216/2008 号条例 (EC) 第 3 条范围内的航空产品、零部件和器具⁽²⁾。

4.

Custom-built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes.

4. 定制评估套件专供专业人士使用，且仅用于研发机构的此类目的。

⁽¹⁾ Council Directive 96/98/EC of 20 December 1996 on marine equipment (OJ L 46, 17.2.1997, p. 25). (1) 1996 年 12 月 20 日关于船用设备的第 96/98/EC 号理事会指令 (《官方公报》L 46 号, 1997 年 2 月 17 日, 第 25 页)。

⁽²⁾ Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC (OJ L 79, 19.3.2008, p. 1). (2) 欧洲议会和理事会 2008 年 2 月 20 日关于民用航空领域共同规则并设立欧洲航空安全局的第 216/2008 号法规 (EC), 该法规废止了理事会第 91/670/EEC 号指令、第 1592/2002 号法规 (EC) 和第 2004/36/EC 号指令 (《官方公报》L 79, 2008 年 3 月 19 日, 第 1 页)。

ANNEX II 附录 II

CONFORMITY ASSESSMENT MODULE A 合格评定模块 A

INTERNAL PRODUCTION CONTROL 内部生产控制

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4 of this Annex, and ensures and declares on his sole responsibility that the radio equipment concerned satisfies the essential requirements set out in Article 3.1. 内部生产控制是一种合格评定程序，根据该程序，制造商应履行本附件第 2、3 和 4 点规定的义务，并自行负责确保和声明相关无线电设备符合第 3 条规定的基本要求。

2. Technical documentation 2. 技术文档

The manufacturer shall establish the technical documentation in accordance with Article 21. 制造商应依照第 21 条编制技术文件。

3. Manufacturing 3. 制造

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured radio equipment with the technical documentation referred to in point 2 of this Annex and with the relevant essential requirements set out in Article 3. 制造商应采取一切必要措施，确保制造过程及其监控能够保证所生产的无线电设备符合本附件第 2 点所述的技术文件以及第 3 条规定的相关基本要求。

4. CE marking and EU declaration of conformity 4. CE 标志和欧盟合格声明

4.1. The manufacturer shall affix the CE marking in accordance with Articles 19 and 20 to each item of radio equipment that satisfies the applicable requirements of this Directive. 制造商应依照第 19 条和第 20 条的规定，在每一件符合本指令适用要求的无线电设备上粘贴 CE 标志。

4.2. The manufacturer shall draw up a written EU declaration of conformity for each radio equipment type and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the radio equipment has been placed on the market. The EU declaration of conformity shall identify the radio equipment for which it has been drawn up. 制造商应为每种无线电设备型号拟定一份书面的欧盟合格声明，并在该无线电设备投放市场后，将其与技术文件一同保存，供国家主管部门查阅，保存期限为 10 年。欧盟合格声明应明确其拟定所针对的无线电设备。

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request. 应相关当局要求，需提供欧盟合格声明的副本。

5. Authorised representative 5. 授权代表

The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.第 4 点中规定的制造商义务可由其授权代表代表制造商并在其责任范围内履行，前提是这些义务在授权书中已明确规定。

ANNEX III 附录 III

CONFORMITY ASSESSMENT MODULES B AND C 合格评定模块 B 和 C

EU-TYPE EXAMINATION AND CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL 基于内部生产控制的欧盟型式检验和型式符合

When reference is made to this Annex, the conformity assessment procedure shall follow Modules B (EU-type examination) and C (Conformity to type based on internal production control) of this Annex.凡提及本附件时，合格评定程序应遵循本附件的模块 B（欧盟型式检验）和模块 C（基于内部生产控制的型式符合性）。

Module B 模块 B

EU-type examination 欧盟型式检验

1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of the radio equipment and verifies and attests that the technical design of the radio equipment meets the essential requirements set out in Article 3.1. 欧盟型式检验是合格评定程序的一部分，在此过程中，公告机构会审查无线电设备的技术设计，并验证和证明该无线电设备的技术设计符合第 3 条规定的基本要求。
2. EU-type examination shall be carried out by assessment of the adequacy of the technical design of the radio equipment through examination of the technical documentation and supporting evidence referred to in point 3, without examination of a specimen (design type).2. 欧盟型式检验应通过审查第 3 点所述的技术文件和支持证据，评估无线电设备技术设计的适当性来进行，无需对样品（设计型式）进行检验。
3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.3. 制造商应向其选择的单个公告机构提交欧盟型式检验申请。

The application shall include: 申请书应包含：

- (a) (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;制造商的名称和地址；如果申请是由授权代表提交的，还应包括该授权代表的名称和地址。
- (b)a written declaration that the same application has not been lodged with any other notified body;一份书面声明，表明未就同一申请向任何其他公告机构提交过申请；

(c) (c) the technical documentation. The technical documentation shall make it possible to assess the radio equipment's conformity with the applicable requirements of this Directive and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the radio equipment. The technical documentation shall contain, wherever applicable, the elements set out in Annex V; 技术文档。技术文档应能使人们对无线电设备是否符合本指令的适用要求进行评估，并应包含对风险的充分分析和评估。技术文档应明确适用要求，并在与评估相关的范围内涵盖无线电设备的设计、制造和操作。技术文档应在适用情况下包含附件 V 中规定的要素。

(d) (d) the supporting evidence for the adequacy of the technical design solution. That supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards have not been applied or have not been fully applied. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility. 证明技术方案充分性的支持证据。该支持证据应提及所使用的任何文件，特别是在未应用或未完全应用相关协调标准的情况下。必要时，支持证据应包括由制造商的适当实验室，或由其他测试实验室代表其并在其责任下，按照其他相关技术规范进行的测试结果。

4. The notified body shall examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the radio equipment. 4. 公告机构应审查技术文件和支持证据，以评估无线电设备技术设计的适当性。

5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations as provided in point 8, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer. 5. 公告机构应拟定一份评估报告，记录根据第 4 点开展的活动及其结果。在不影响第 8 点规定的义务的前提下，公告机构仅可在获得制造商同意后，全部或部分公开该报告的内容。

6. Where the type meets the requirements of this Directive that apply to the radio equipment concerned, the notified body shall issue an EU-type examination certificate to the manufacturer. That certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the aspects of the essential requirements covered by the examination, the conditions (if any) for its validity and the necessary data for identification of the assessed type. The EU-type examination certificate may have one or more annexes attached. 6. 当该型号符合本指令中适用于相关无线电设备的要求时，公告机构应向制造商颁发欧盟型式检验证书。该证书应包含制造商的名称和地址、检验结论、检验所涵盖的基本要求方面、证书的有效条件（如有）以及用于识别所评估型号的必要数据。欧盟型式检验证书可附带一个或多个附件。

The EU-type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured radio equipment with the examined type to be evaluated and to allow for in-service control. 欧盟型式检验证书及其附件应包含所有相关信息，以便评估所制造的无线电设备与经检验型式的符合性，并便于在役控制。

Where the type does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal. 如果该类型不符合本指令的适用要求，公告机构应拒绝签发欧盟类型检查证书，并应相应通知申请人，同时给出拒绝的详细理由。

7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly. 7. 公告机构应随时了解公认技术水平的任何变化，这些变化表明已批准的类型可能不再符合本指令的适用要求，并应确定此类变化是否需要进一步调查。如果需要，公告机构应相应地通知制造商。

The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the radio equipment with the essential requirements of this Directive or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate. 制造商应将经批准型号的所有修改情况通知持有与欧盟型式检验证书相关的技术文件的公告机构，这些修改可能会影响无线电设备对本指令基本要求的符合性，或影响该证书的有效性条件。此类修改需要通过原始欧盟型式检验证书上添加内容的形式获得额外批准。

8. Each notified body shall inform its notifying authority concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted. 8. 每个公告机构应将其颁发或撤回的欧盟型式检验证书及/或其任何补充文件通知其公告主管部门，并应定期或应要求向其公告主管部门提供被拒绝、暂停或受到其他限制的此类证书及/或其任何补充文件的清单。

Each notified body shall inform the other notified bodies concerning the EU-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued. 每个公告机构应将其拒绝、撤回、暂停或以其他方式限制的欧盟型式检验证书及/或其任何增补通知其他公告机构；并应要求，将其签发的此类证书及/或其任何增补通知其他公告机构。

Each notified body shall inform the Member States of EU-type examination certificates it has issued and/or additions thereto in those cases where harmonised standards the references of which have been published in the *Official Journal of the*

European Union have not been applied or not been fully applied. The Member States, the Commission and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Member States and the Commission may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer for 10 years after the radio equipment has been assessed or until the expiry of the validity of that certificate. 每个公告机构均应在未应用或未完全应用其引用已在《欧盟官方公报》上公布的协调标准的情况下，将其颁发的欧盟型式检验证书及/或其补充件通知各成员国。应请求，各成员国、委员会及其他公告机构可获得欧盟型式检验证书及/或其补充件的副本。应请求，各成员国和委员会可获得技术文件以及公告机构所开展检验的结果的副本。公告机构应保存欧盟型式检验证书、其附件和补充件，以及包括制造商提交的文件在内的技术档案，保存期限为无线电设备完成评估后 10 年，或直至该证书有效期届满。

9. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the radio equipment has been placed on the market. 9. 制造商应在无线电设备投放市场后 10 年内，保存一份欧盟型式检验证书及其附件和补充文件，连同技术文件一并供国家主管部门查阅。

10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate. 10. 制造商的授权代表可提交第 3 点所述的申请，并履行第 7 点和第 9 点规定的义务，前提是这些内容在授权书中已明确规定。

Module C 模块 C

Conformity to type based on internal production control 基于内部生产控制的类型一致性

1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares that the radio equipment concerned is in conformity with the type described in the EU-type examination certificate and satisfies the requirements of this Directive that apply to it. 1. 基于内部生产控制的符合性是合格评定程序的一部分，根据该程序，制造商需履行第 2 点和第 3 点规定的义务，并确保且声明相关无线电设备符合欧盟型式检验证书中所述的型式，且满足本指令中适用于该设备的要求。

2. Manufacturing 2. 制造

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured radio equipment with the approved type described in the EU-type examination certificate and with the requirements of this Directive that apply to it. 制造商应采取一切必要措施，确保制

造过程及其监控能够保证所生产的无线电设备符合欧盟型式检验证书中所述的批准型式，并符合本指令中适用于该设备的要求。

3. CE marking and EU declaration of conformity 3. CE 标志和欧盟符合性声明

3.1. The manufacturer shall affix the CE marking in accordance with Articles 19 and 20 to each item of radio equipment that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive. 制造商应依照第 19 条和第 20 条的规定，在每一件符合欧盟型式检验证书所述型式且满足本指令适用要求的无线电设备上粘贴 CE 标志。

3.2. The manufacturer shall draw up a written EU declaration of conformity for each radio equipment type and keep it at the disposal of the national authorities for 10 years after the radio equipment has been placed on the market. The EU declaration of conformity shall identify the radio equipment type for which it has been drawn up. 制造商应为每种无线电设备型号拟定一份书面的欧盟符合性声明，并在该无线电设备投放市场后将其留存，供国家主管部门查阅，保存期限为 10 年。欧盟符合性声明应明确其拟定所针对的无线电设备型号。

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request. 应相关当局要求，需提供欧盟合格声明的副本。

4. Authorised representative 4. 授权代表

The manufacturer's obligations set out in point 3 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. 第 3 点中规定的制造商义务，可由其授权代表代表制造商并在其责任范围内履行，前提是这些义务已在授权书中明确规定。

ANNEX IV 附录四

CONFORMITY ASSESSMENT MODULE H 合格评定模块 H

CONFORMITY BASED ON FULL QUALITY ASSURANCE 基于全面质量保证的合规性

1. Conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the radio equipment concerned satisfies the requirements of this Directive that apply to it. 1. 基于全面质量保证的合格评定是一种合格评定程序，根据该程序，制造商需履行第 2 点和第 5 点规定的义务，并自行负责确保相关无线电设备符合本指令中适用于该设备的要求，并对此作出声明。

2. Manufacturing 2. 制造

The manufacturer shall operate an approved quality system for design, manufacture, final radio equipment inspection and testing of the radio equipment concerned as

specified in point 3 and shall be subject to surveillance as specified in point 4. 制造商应按照第 3 点的规定，对相关无线电设备的设计、制造、最终无线电设备检验和测试实施经批准的质量体系，并应接受第 4 点规定的监督。

3. Quality system 3. 质量体系

3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the radio equipment concerned. 制造商应就相关无线电设备，向其选择的公告机构提交质量体系评估申请。

The application shall include: 申请书应包含：

(a) (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well; 制造商的名称和地址；如果申请是由授权代表提交的，还应包括该授权代表的名称和地址。

(b) the technical documentation for each radio equipment type intended to be manufactured. The technical documentation shall contain, wherever applicable, the elements set out in Annex V; 拟生产的每种无线电设备类型的技术文档。技术文档应包含附件五所列的相关内容（如适用）。

(c) (c) the documentation concerning the quality system; and 有关质量体系的文件；以及

(d) (d) a written declaration that the same application has not been lodged with any other notified body. 一份书面声明，表明同一申请未提交给任何其他公告机构。

3.2. The quality system shall ensure compliance of the radio equipment with the requirements of this Directive that apply to it. 质量体系应确保无线电设备符合本指令中适用于它的要求。

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. That quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records. 制造商采用的所有要素、要求和规定应以书面政策、程序和指令的形式，系统有序地形成文件。该质量体系文件应能对质量方案、计划、手册和记录作出一致的解释。

It shall, in particular, contain an adequate description of: 它尤其应包含对以下内容的充分描述：

(a) (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality; 质量目标以及管理层在设计 and 产品质量方面的组织结构、职责与权限；

(b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards will not be applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to the radio equipment will be met; 技术设计规范，包括将采用的标准；以及在相关协调标准不会被完全采用的情况下，将用于确保本指令中适用于无线电设备的基本要求得到满足的方法。

(c) (c) the design control and design verification techniques, processes and systematic

actions that will be used when designing radio equipment pertaining to the radio equipment type covered;在设计及所涵盖的无线电设备类型相关的无线电设备时，将采用的设计控制、设计验证技术、流程和系统性措施；

(d) (d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;将使用的相应制造、质量控制和质量保证技术、流程及系统性措施；

(e) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;在制造前、制造过程中及制造后将要进行的检查和测试，以及进行这些检查和测试的频率；

(f) the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications of the personnel, etc.;质量记录，如检验报告和测试数据、校准数据、有关人员资质的报告等；

(g) (g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system. 监控所需设计和产品质量的达成情况以及质量体系有效运行的方法。

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. 公告机构应对质量体系进行评估，以确定其是否满足第 3.2 点所述的要求。

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard. 对于质量体系中符合相关协调标准对应规范的要素，应推定其符合这些要求。

In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant radio equipment field and radio equipment technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1(b) to verify the manufacturer's ability to identify the applicable requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the radio equipment with those requirements. 除了具备质量管理体系方面的经验外，审核团队还应至少有一名成员具有相关无线电设备领域和所涉无线电设备技术的评估员经验，并且熟悉本指令的适用要求。审核应包括对制造场所的评估访问。审核团队应审查第 3.1(b) 点所述的技术文件，以核实制造商识别本指令适用要求以及开展必要检查的能力，确保无线电设备符合这些要求。

The manufacturer or his authorised representative shall be notified of the decision. 应将该决定通知制造商或其授权代表。

The notification shall contain the conclusions of the audit and the reasoned assessment decision. 通知应包含审核结论和有理有据的评估决定。

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient. 制造商应承诺履行经批准的质量体系所产生的义务，并对该体系进行维护，使其保持适当和有效。

- 3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system. 制造商应将质量管理体系的任何拟议变更通知已批准该体系的公告机构。

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary. 公告机构应评估所有拟议变更，并决定修改后的质量体系是否仍能满足第 3.2 点所述要求，或者是否需要重新评估。

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision. 它应将其决定通知制造商。通知应包含审查结论和有理由的评估决定。

4. Surveillance under the responsibility of the notified body 4. 公告机构负责的监督

- 4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system. 监督的目的是确保制造商切实履行经批准的质量体系所产生的义务。

- 4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular: 为评估之目的，制造商应允许公告机构进入设计、制造、检验、测试和存储场所，并向其提供所有必要信息，特别是：

(a) (a) the quality system documentation; 质量管理体系文件；

(b) (b) the quality records as provided for by the design part of the quality system, such as results of analyses, calculations, tests, etc.; 质量体系设计部分规定的质量记录，如分析结果、计算结果、测试结果等；

(c) (c) the quality records as provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, reports concerning the qualifications of the personnel, etc. 质量体系中制造部分规定的质量记录，例如检验报告和测试数据、校准数据、有关人员资质的报告等。

- 4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report. 公告机构应进行定期审核，以确保制造商维持并应用该质量体系，并应向制造商提供审核报告。

- 4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits, the notified body may, if necessary, carry out radio equipment tests, or have them carried out, in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report. 此外，公告机构可能会对制造商进行突击检查。在这类检查期间，公告机构必要时可进行或委托他人进行无线电设备测试，以核查质量体系的正常运行情况。公告机构应向制造商提供检查报告；若进行了测试，还应提供测试报告。

5. CE marking and EU declaration of conformity 5. CE 标志和欧盟符合性声明

5.1. The manufacturer shall affix the CE marking in accordance with Articles 19 and 20 and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each item of radio equipment that satisfies the applicable requirements set out in Article 3. 制造商应根据第 19 条和第 20 条的规定粘贴 CE 标志, 并且在第 3.1 点所述的公告机构的责任下, 将该机构的识别号码附加到每一件符合第 3 条规定的适用要求的无线电设备上。

5.2. The manufacturer shall draw up a written EU declaration of conformity for each radio equipment type and keep it at the disposal of the national authorities for 10 years after the radio equipment has been placed on the market. The EU declaration of conformity shall identify the radio equipment type for which it has been drawn up. 制造商应为每种无线电设备型号拟定一份书面的欧盟符合性声明, 并在该无线电设备投放市场后将其留存, 供国家主管部门查阅, 保存期限为 10 年。欧盟符合性声明应明确其拟定所针对的无线电设备型号。

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request. 应相关当局要求, 需提供欧盟合格声明的副本。

6. The manufacturer shall, for a period ending 10 years after the radio equipment has been placed on the market, keep at the disposal of the national authorities: 6. 制造商应在无线电设备投放市场后 10 年届满前, 将相关资料留存, 供国家主管部门查阅:

- (a) (a) the technical documentation referred to in point 3.1; 第 3.1 点中提及的技术文件;
- (b) the documentation concerning the quality system referred to in point 3.1; 第 3.1 点所提及的有关质量管理体系的文件;
- (c) (c) the change referred to in point 3.5, as approved; 经批准的 3.5 点所指的变更;
- (d) (d) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4. 第 3.5 点、第 4.3 点和第 4.4 点所提及的公告机构的决定和报告。

7. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted. 7. 每个公告机构应将已颁发或撤销的质量体系批准情况通知其通知机构, 并应定期或应要求向其通知机构提供被拒绝、暂停或以其他方式受限的质量体系批准清单。

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued. 每个公告机构应将其拒绝、暂停或撤销的质量体系批准情况通知其他公告机构; 并应要求, 将其颁发的质量体系批准情况告知其他公告机构。

8. Authorised representative 8. 授权代表

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that

they are specified in the mandate.制造商在第 3.1、3.5、5 和 6 点中规定的义务，可由其授权代表代表其履行，并由其承担责任，前提是这些义务在授权范围内有明确规定。

ANNEX V 附录五

CONTENTS OF TECHNICAL DOCUMENTATION 技术文档内容

The technical documentation shall, wherever applicable, contain at least the following elements:技术文档在适用情况下应至少包含以下要素：

- (a) (a) a general description of the radio equipment including:无线电设备的一般描述，包括：
 - (i) (i) 无线电设备支持某些功能，以确photographs or illustrations showing保只有在已证明无线电设备与软件的组external features, marking and internal合符合要求的情况下，才能将软件加载到layout;显示外部特征、标识和内部布局的该无线电设备中。照片或插图；
 - (ii) (ii) versions of software or firmware affecting compliance with essential requirements;影响基本要求符合性的软件或固件版本；
 - (iii) user information and installation instructions;用户信息和安装说明；
- (b)conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits and other relevant similar elements;组件、子组件、电路及其他相关类似元素的概念设计、制造图纸和方案；
- (c) (c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the radio equipment;理解这些图纸、方案以及无线电设备操作所必需的描述和解释；
- (d) (d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union*, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements set out in Article 3, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;已在《欧盟官方公报》上公布参考信息的、全部或部分适用的协调标准清单；若未适用这些协调标准，则需包含为满足第 3 条所列基本要求而采用的解决方案说明，包括所适用的其他相关技术规范清单。如协调标准仅部分适用，技术文件应明确说明所适用的部分。
- (e) copy of the EU declaration of conformity;欧盟符合性声明副本；
- (f)where the conformity assessment module in Annex III has been applied, copy of the EU-type examination certificate and its annexes as delivered by the notified body involved;在适用附件 III 中的合格评定模块的情况下，由相关公告机构出具的欧盟型式检验证书及其附件的副本；
- (g) (g) results of design calculations made, examinations carried out, and other relevant

similar elements;设计计算结果、所进行的检验以及其他相关的类似要素;

(h) (h) 无线电设备支持某些功能, 以方便残障用户使用; test reports; 测试报告;

(i) (i) 无线电设备支持某些功能, 以确保只有在已证明无线电Article 10(2) and of the inclusion or not of information on the设备与软件的组合符合要求的情况下, 才能将软件加载到该无线电第(2)款要求的说明, 以及是否根据第10条第(10)款电设备中。 packaging in accordance with Article 10(10).关于符合第10条第(10)款电设备中。 在包装上包含相关信息的说明。

ANNEX VI 附件六

EU DECLARATION OF CONFORMITY (No XXX) (1) 欧盟符合性声明 (编号 XXX) (1)

1.

Radio equipment (product, type, batch or serial number):

1. 无线电设备 (产品、型号、批次或序列号):

2.

Name and address of the manufacturer or his authorised representative:

2. 制造商或其授权代表的名称和地址:

3.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

3. 本符合性声明由制造商单独负责发布。

4.

Object of the declaration (identification of the radio equipment allowing traceability; it may include a colour image of sufficient clarity where necessary for the identification of the radio equipment):

4. 声明目的（对可追溯的无线电设备进行识别；必要时可包含清晰度足够的彩色图像，以用于无线电设备的识别）：

5.

The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:上述声明的标的符合相关的欧盟协调立法：

Directive 2014/53/EU 2014/53/EU 号指令

Other Union harmonisation legislation where applicable 其他适用的欧盟协调立法

6.

References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared. References must be listed with their identification number and version and, where applicable, date of issue:

6. 所使用的相关协调标准的引用，或声明符合的其他技术规范的引用。引用必须列出其识别编号和版本，如适用，还需列出发布日期：

7.

Where applicable, the notified body ... (name, number) ... performed ... (description of intervention) ... and issued the EU-type examination certificate: ...

7. 在适用情况下，公告机构.....（名称、编号）.....执行了.....（干预说明）.....并颁发了欧盟型式检验证书：.....

8.

Where applicable, description of accessories and components, including software, which allow the radio equipment to operate as intended and covered by the EU declaration of conformity:

8. 在适用情况下，对使无线电设备能够按预期运行并包含在欧盟符合性声明中的附件和组件（包括软件）的描述：

9.

Additional information: 补充信息：

Signed for and on behalf of: ... 代表.....签署：

(place and date of issue): (签发地点和日期)：

(name, function) (signature): (姓名、职务) (签名)：

(*) It is optional for the manufacturer to assign a number to the EU declaration of conformity. (*) 制造商可自行选择是否为欧盟符合性声明分配编号。

ANNEX VII 附录七

SIMPLIFIED EU DECLARATION OF CONFORMITY 简化版欧盟合格声明

The simplified EU declaration of conformity referred to in Article 10(9) shall be provided as follows:第 10 条第 9 款所提及的简化版欧盟合格声明应按以下方式提供：

Hereby, [Name of manufacturer] declares that the radio equipment type [designation of type of radio equipment] is in compliance with Directive 2014/53/EU.据此，[制造商名称]声明，型号为 [无线电设备型号名称]的无线电设备符合 2014/53/EU 号指令。

The full text of the EU declaration of conformity is available at the following internet address:欧盟符合性声明全文可在以下互联网地址获取：

ANNEX VIII 附录八

CORRELATION TABLE 对照表

Directive 1999/5/EC 1999/5/EC 号指令	This Directive 本指令
Article 1 第 1 条	Article 1 第 1 条
Article 2 第 2 条	Article 2 第 2 条
Article 3(1) and (2) 第 3 条第 (1) 款和第 (2) 款	Article 3(1) and (2) 第 3 条第 (1) 款和第 (2) 款
Article 3(3) and Article 15a 第 3 条第 3 款和第 15a 条	Article 3(3), with the exception of Article 3(3)(i), and Article 44 第 3 条第 3 款 (第 3 条第 3 款第 i 项除外) 和第 44 条

Article 4(1) and Articles 13 to 15 第 4 条第 1 款及第 13 至 15 条	Articles 8 and 45 第 8 条和第 45 条
Article 4(2) 第 4 条第 2 款	--
Article 5(1) 第 5 条第 1 款	Article 16 第 16 条
Article 5(2) and (3) 第 5 条第 (2) 和 (3) 款	--
Article 6(1) 第 6 条第 1 款	Article 6 第 6 条
Article 6(2) 第 6 条第 2 款	--
Article 6(3) 第 6 条第 3 款	Article 10(8), (9) and (10) 第 10 条第 (8)、(9) 和 (10) 款
Article 6(4) 第 6 条第 4 款	--
Article 7(1) and (2) 第 7 条第 (1) 和 (2) 款	Article 7 第 7 条
Article 7(3), (4) and (5) 第 7 条第 3 款、第 4 款和第 5 款	--
Article 8(1) and (2) 第 8 条第 (1) 和 (2) 款	Article 9 第 9 条
Article 8(3) 第 8 条第 3 款	--
Article 9 第 9 条	Articles 39 to 43 第 39 至 43 条
Article 10 第 10 条	Article 17 第 17 条
Article 11 第 11 条	Articles 22 to 38 第 22 至 38 条
Article 12 第 12 条	Articles 19 and 20 and Article 10(6) and (7) 第 19 条、第 20 条以及第 10 条第 6 款和第 7 款
Article 16 第 16 条	--
Article 17 第 17 条	Article 47 第 47 条
Article 18 第 18 条	Article 48 第 48 条
Article 19 第 19 条	Article 49 第 49 条
Article 20 第 20 条	Article 50 第 50 条
Article 21 第 21 条	Article 51 第 51 条
Article 22 第 22 条	Article 52 第 52 条
Annex I 附件一	Annex I 附件一
Annex II 附件二	Annex II 附件二
Annex III 附件三	--
Annex IV 附件四	Annex III 附件三
Annex V 附录五	Annex IV 附件四
Annex VI 附录六	Article 26 第 26 条

Annex VII(1) to (4) 附件七（1）至（4）	Articles 19 and 20 第 19 条和第 20 条
Annex VII(5) 附件七（5）	Article 10(10) 第 10 条第 10 款

STATEMENT OF THE EUROPEAN PARLIAMENT 欧洲议会声明

The European Parliament considers that only when and insofar as implementing acts in the sense of Regulation (EU) No 182/2011 are discussed in meetings of committees, can the latter be considered as ‘comitology committees’ within the meaning of Annex I to the Framework Agreement on the relations between the European Parliament and the European Commission. Meetings of committees thus fall within the scope of point 15 of the Framework Agreement when and insofar as other issues are discussed. 欧洲议会认为，只有当委员会会议讨论《(欧盟)第 182/2011 号条例》所指的实施法案，且讨论范围仅限于此情况下，这些委员会才能被视为《欧洲议会与欧盟委员会关系框架协议》附件一所指的“欧盟委员会附属委员会”。而当委员会会议讨论其他议题，且讨论范围仅限于此情况下，其则属于该框架协议第 15 点的适用范围。