



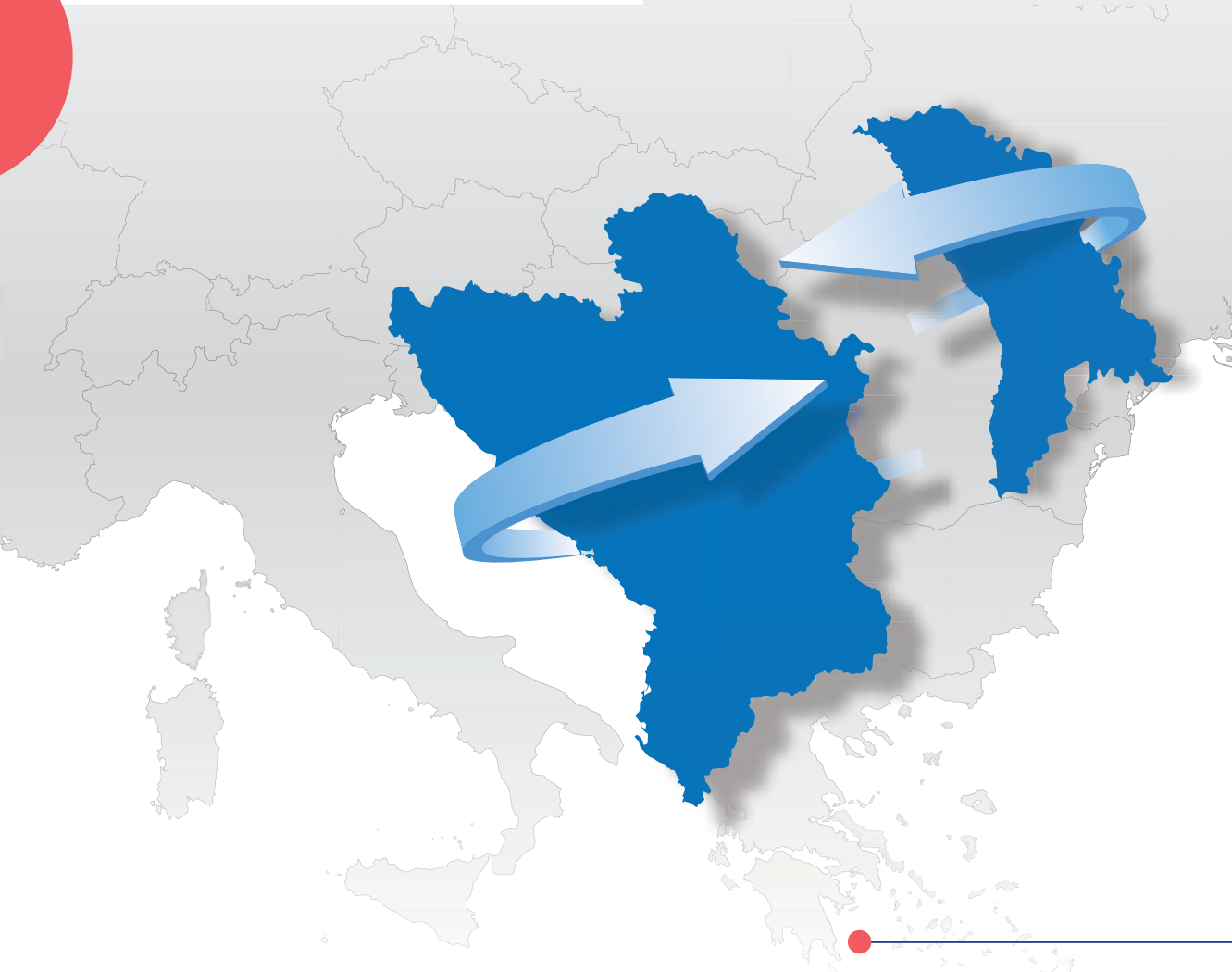
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Guidelines for electrical products

Implementation of Low Voltage (2014/30/EU) and
Electromagnetic Compatibility (2014/35/EU) Directives



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Table of contents

1. Acronyms and abbreviations	4
2. Introduction	5
3. LVD conformity assessment flowchart	6
3.1 Appendix 1 – Equipment within the scope of LVD and exclusions from the scope	7
3.2 Appendix 2 – Defining the harmonised standards for the equipment	8
3.3 Appendix 3 – When harmonised standards are not available for the equipment	10
3.4 Appendix 4 – Performance of product safety tests	11
3.5 Appendix 5 – Compilation of the LVD technical documentation	12
3.6 Appendix 6 – Declaration of conformity and conformity assessment marking	13
3.7 Appendix 7 – Internal production control	13
3.8 Appendix 8 – Obligations of the manufacturer in the market surveillance process	14
3.9 EU Market Surveillance Actions	14
4. EMCD conformity assessment flowchart	15
4.1 Appendix 1 – Equipment within the scope of the EMCD and exclusions	17
4.2 Appendix 2 – Defining the harmonised standards for the equipment	18
4.3 Appendix 3 – When harmonised standards are not available for the equipment	19
4.4 Appendix 4 – Performance of EMC tests and measurements	21
4.5 Appendix 5 – Compilation of the LVD technical documentation	23
4.6 Appendix 6 – Declaration of conformity and conformity assessment marking	24
4.7 Appendix 7 – Internal production control	25
4.8 Appendix 8 – Obligations of the manufacturer in the market surveillance process	25
4.9 EU market surveillance actions	25
5. Bibliography	26

1. Acronyms and abbreviations

Acronym/ abbreviation	Explanation
ATEX directive	Electrical equipment for use in an explosive atmosphere It is covered by the ATEX-Directive 2014/34/EU
Blue Guide	The 'Blue Guide' on the implementation of EU product rules – latest revision of 2022
CEN	European Committee for Standardisation
CENELEC	European Committee for Electrotechnical Standardization
CISPR	International Special Committee on Radio interference (Comité International Spécial des Perturbations Radioélectriques)
EMC	Electromagnetic Compatibility
EMC ADCO	EMC Administrative Co-operation Working Group of market surveillance authorities
EMCD	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)
EU	European Union
HAS	Harmonised standard
IEC	International Electro-technical Commission
IECEE	IEC system for conformity testing and certification of electro technical Equipment and Components also known as CB-scheme
ISO	International Organization for Standardization
LED	Light emitting diode
LVD	Directive 2014/35/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 the making available on the market of electrical equipment designed for use within certain voltage limits.
OJEU and OJ R&TTE Directive or R&TTED	Official Journal of the European Union 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)
RED	Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 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 (OJ L 153, 22.5.2014, p 62).

2. Introduction



The guidelines covered in this document are related to the implementation of the Low Voltage Directive and the Electromagnetic Compatibility Directive of the EU acquis.

PLEASE READ THE FOLLOWING DISCLAIMERS

Disclaimer:

The reference documents used for developing these guidelines are mentioned in the text and a list is given in the bibliography at the end of the document.

To make it easily understandable for the manufacturer, this guide uses flowcharts for the application of the LVD and EMCD. These show the steps to be taken to obtain and to keep compliance with both directives, i.e. conformity assessment.

The terminology used in this document follows the definitions given in the LVD [1] and EMCD [2].

In this guidance document there are references to Notified Bodies and other procedures which apply to EU member states. This is done because these requirements apply to products that are to be exported to EU member states.

- 01.** This is a guidance document for facilitating the implementation of the LVD [1] and EMCD[2], primarily by manufacturers. The legally binding documents are the legal texts of the LVD [1] and EMCD [2] and when applicable mandated supporting documents issued by the lawmakers and regulators of the relevant parties.
- 02.** Standards and legal documents mentioned in the text refer to the version in force as of the date of these guidelines. However, when using legal documents and standards the version in force should be verified and used.
- 03.** The guidelines used “shall” when describing requirements arising from legal documents and “should” when describing possible ways of meeting the requirements.

3. LVD [1] conformity assessment flowchart

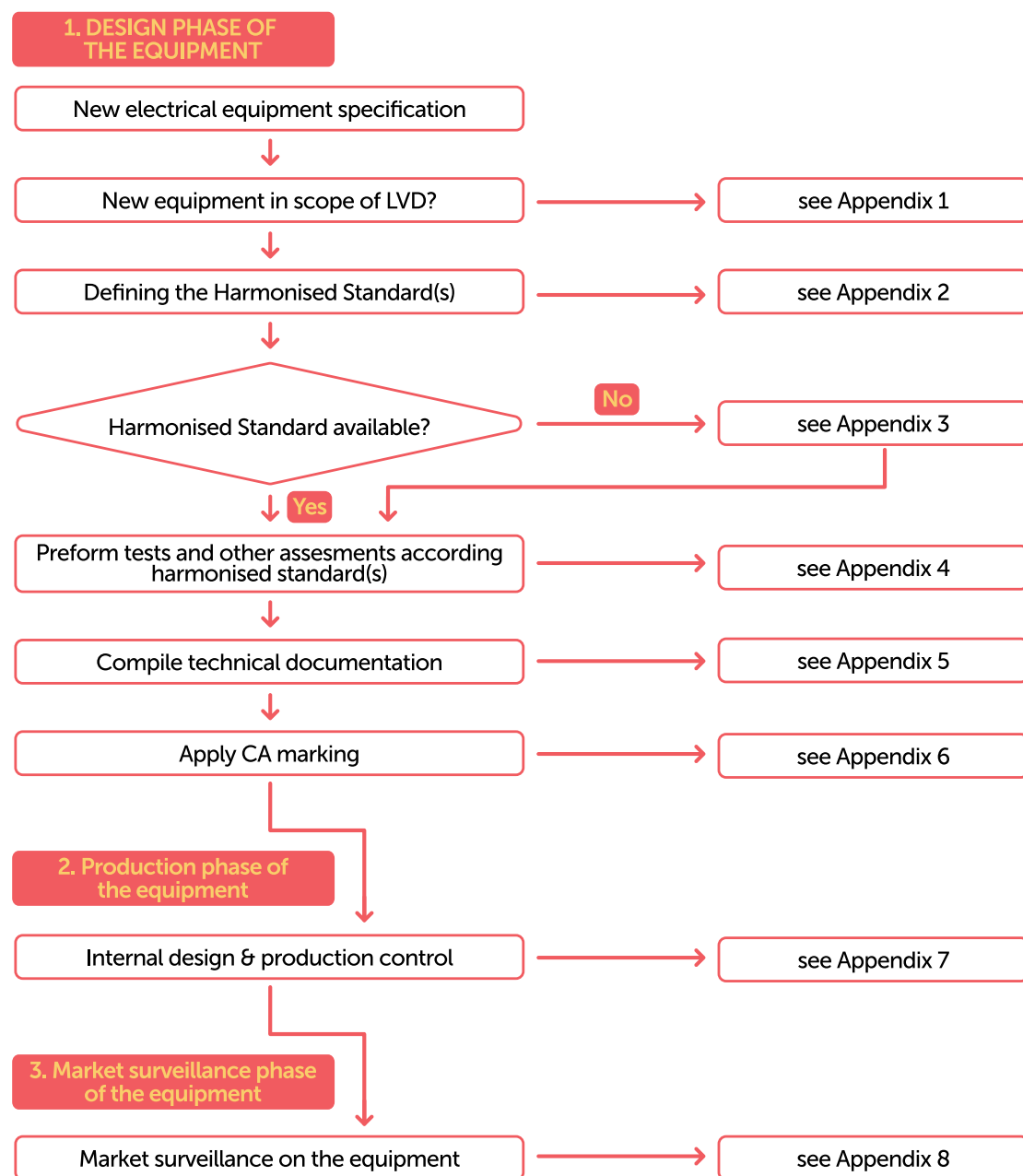


Fig. 1: overall LVD conformity assessment

The flowchart above covers the different conformity assessment phases of the equipment which has to comply with the LVD [1]. These are:

- 01.** Design phase of the equipment
- 02.** Production phase of the equipment

03. Market surveillance phase of the equipment

For some steps in the above flowchart more specific guidance is provided in the 7 appendices (see further in this guide).

3.1 Appendix 1 – Equipment within the scope of LVD[1] and exclusions from the scope

The LVD [1] is a “full harmonisation, safety Directive” in the sense that it covers all safety aspects of electrical equipment, not just the electrical risks. However, there are some limitations to its scope.

Voltage levels

The LVD's [1] scope is limited to equipment the inputs or outputs of which are connected to voltage sources in the range of 50 to 1000 Volts AC (alternating current) and 75 to 1500 Volts DC (direct current). However, voltages higher than these levels can be generated inside the equipment.

Excluded equipment

The list of excluded equipment is clearly stated in cl. 58 of the EU LVD Guide [3]. The reasons for the exemptions, for some electrical equipment, are that they are covered by other more specific Union acts, for example ATEX equipment, medical equipment, equipment used in vehicles or ships, etc.

Other electrical equipment is excluded because of different reasons, for example mains plugs, because these devices are not harmonized in Europe due to different plug types.

In Annex VII of the official EU LVD Guide [3], examples are provided of both electrical

equipment which is within the scope of the LVD [1] and outside the scope of the LVD [1].

The Machinery Directive 2006/42/EC [5] clarifies the borderline between the scope of the Machinery Directive [5] and the LVD [1] in order to provide greater legal certainty for manufacturers. Certain categories of electrical and electronic machinery products are excluded from the scope of the Machinery Directive [5] as set out in its Article 1, point 2 subpoint (k):

“

(k) electrical and electronic products falling within the following areas, insofar as they are covered by the Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits:

- household appliances intended for domestic use;
- audio and video equipment;
- information technology equipment;
- ordinary office machinery;
- low-voltage switchgear and control gear;
- electric motors.

3.2 Appendix 2 – Defining the harmonised standards for the equipment

The use of a harmonised standard by a manufacturer, will provide presumption of conformity with the LVD [1]. This is a very important and far-reaching statement, which provides among other benefits, legal certainty to the manufacturer. A harmonised standard published in the Official Journal of the European Union (OJEU) has the recognition that its content covers the essential requirements (Annex 1 of 2014/35/EU) of the LVD [1].

In 2016 the European Commission started with a review of the harmonised standards (HAS) to verify whether these standards did suitably cover the essential requirements. This work carried out by “the HAS consultants’ system” is currently ongoing (there are about 1000 LVD harmonised standards [14]). For a description of the HAS assessment process see, https://boss.cen.eu/developingdeliverables/pages/en/pages/has_assessment_process/

The role of the European harmonised standards has been boosted with harmonised legislation under the New Legislative Framework, since the coming into force of the Regulation 1025/2012/EU [6] on European Standardisation. Harmonised standards are developed by the European Standardisation Organisations officially recognised by Regulation (EU) No 1025/2012 [6] as providers of European standards.

The Commission may request the European Standardisation Organisations to develop standards responding to regulatory

needs - or policy needs - by submitting standardisation requests (Art. 10(1) of the Regulation 1025/2012 [6]). In case European Standardisation Organisations accept the request, they are obliged to develop a standard (or set of standards) covering the requirements defined or referenced to in the standardisation request. Regulation (EU) No 1025/2012 [6] establishes the process of assessment of draft harmonised standards which, in case of positive assessment of the Commission with the support of the HAS Consultants, leads to the decision to publish their references in the Official Journal of the European Union (OJEU) as a prerequisite for a legal effect, i.e. ‘presumption of conformity’.

In practice this means that each harmonised standard needs an annex ZZ (at the end of the EN harmonised standard) in which a list is given showing the correspondence between the 10 essential requirements of the LVD and the clauses of the harmonised standard. The new HAS assessment system also ensures that harmonised standards are supported by a risk assessment document: IEC 116:2018 Guidelines for safety related risk assessment and risk reduction for low voltage equipment [8] and the European equivalent Guide 32 of CENELEC [11]. This guide is useful for the manufacturer, as will be explained in the next appendix.

Table: ZZ.1 - Correspondence between this European standard and Annex I of Directive 2014/35/EU [2014 OJ L96]

Safety objectives of Directive 2014/35/EU (Annex I)	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
1. General conditions		
1 (a) the essential characteristics, the recognition and observance of which will ensure that electrical equipment will be used safely and in applications for which it was made, shall be marked on the electrical equipment, or, if this is not possible, on an accompanying document	5.1 5.2 5.4	
1 (b) the electrical equipment, together with its component parts, shall be made in such a way as to ensure that it can be safely and properly assembled and connected	6.6 6.10 6.11 Annex F	
1 (c) the electrical equipment shall be so designed and manufactured as to ensure that protection against the hazards set out in points 2 and 3 is assured, providing that the equipment is used in applications for which it was made and is adequately maintained	5.4 17 (for hazards not covered by clauses 6-16) See also the details in points 2 and 3	

Figure 2: the annex ZZ (from EN 61010-1 partly shown)

Annex D - Tool for the application of this CENELEC Guide

After having identified the hazards associated with the LV equipment and after having estimated and evaluated the associated risks, the result of the risk assessment can be documented in the following table. The left column lists the hazards described in Annex A. The 2nd column is the result of the hazard identification carried out by Technical Committees and the 3rd column documents the solution for reducing the risk associated with the relevant hazard. A simple verification by Technical Committees in the 3rd column is e.g. the reference to a horizontal safety standard or group safety standard or a suitable standard from another SDO, e.g. ISO. Also a technical solution which is not subject to a standard may be described.

Table D.1 - Risk assessment documentation of EN 61010-1:2010+A1:2016

Requirement	Relevant yes / no?	Fulfilled by clause(s)
A.2 Preliminary observations	Yes	Application of Annex A of this Guide
A.3 Safety integration	Yes	Application of this Guide, in particular of the “3-step-method” - Inherently safe design measures - Risk reduction measures - User information
A.4 Protection against electrical hazards		
• leakage current	Yes	4.4.2.3 6.3
• energy supply	Yes	6.11, 9.6
• stored charges	Yes	6.3, 6.6.2, 6.10.3

Figure 3: the risk assessment table of CENELEC Guide 32

3.3 Appendix 3 – When harmonised standards are not available for the equipment

Although there are about 1000 LVD harmonised standards [14] published in the OJ, there are still some areas of the LVD which are not harmonised. Also, for some equipment there are not any harmonised standards or even IEC standards. For these situations, it will be more difficult for the manufacturer to prove conformity with the essential requirements of the LVD [1].

A method which is normally used in absence of harmonised standards or other standards, is that the manufacturer seeks to find a harmonised standard for an electrical equipment that has similar characteristics and risks as the equipment in question. The scope of the candidate harmonised standard should be read for that purpose.

When there is a similarity then the manufacturer shall perform a risk assessment according to CENELEC Guide 32 [11], on the equipment to identify the hazards that are not covered in the standard for an equipment with similar characteristics. The manufacturer may also contact the CENELEC TC (Technical Committee) responsible for that similar standard and ask them to supply the risk assessment document.

The EU LVD guide [3] provides for a convenient listing of harmonised standards which may be used for both the LVD [1] and Machinery Directive [5] or separately.

Standard reference	To be listed under LVD (2014/35/EU)	To be listed under MD (2006/42/EC)
EN 50410, Decorative robots	☐	☒
EN 50416, Commercial electric conveyor dishwashing machines	☐	☒
EN 50569, Commercial spin extractors	☐	☒
EN 50570, Commercial tumble dryers	☐	☒
EN 50571, Commercial washing machines	☐	☒
prEN 50xxx, Commercial ironers	☐	☒
EN 60335-1, General requirements	☒	☒
EN 60335-2-2, Vacuum cleaners and water-suction cleaning appliances	☒	☐
EN 60335-2-3, Electric irons	☒	☐
EN 60335-2-4, Spin extractors	☒	☐
EN 60335-2-5, Dishwashers	☒	☐
EN 60335-2-6, Stationary cooking ranges, hobs, ovens and similar appliances	☒	☐
EN 60335-2-7, Washing machines	☒	☐

Figure 4: LVD harmonised standards versus Machinery directive harmonised standards

Note that the LVD [1] and the Machinery Directive [5] are mutually exclusive in use, this means that an equipment cannot be declared compliant with both the LVD [1] and Machinery Directive [5] on the declaration of conformity.

3.4 Appendix 4 – Performance of product safety tests

If the harmonised standards route is followed, the manufacturer shall perform or shall let an external laboratory perform, the tests and other assessments (verifications or inspections) according to the relevant harmonised standard(s). Historically, accuracy information or measurement uncertainty of these tests were not always included in the harmonised standards. For this reason, a specific part on measurement uncertainty for testing of electrical products has been added to this guideline.

Measurement uncertainty according IEC guide 115:2023

No measurement is perfect, and the imperfections give rise to error of measurement in the result. Consequently, the result of a measurement is only an approximation of the measured value (measurand) and is only complete when accompanied by a statement of the uncertainty of that approximation. Indeed, because of measurement uncertainty, a true value can never be known.

IEC Guide 115:2023 presents a practical approach to the application of uncertainty of measurement to conformity assessment activities in the electrotechnical sector. It is specifically conceived for use in IECCE Schemes as well as by testing laboratories engaged in testing electrical products to national/local safety standards. It describes the application of uncertainty of measurement principles and provides guidance on making uncertainty of measurement calculations.

It also gives some examples relating to uncertainty of measurement calculations for product conformity assessment testing.

Examples of sources of measurement uncertainty are:

01. Instrument calibration data
02. Temperature changes during test
03. Humidity and pressure changes during test
04. Electrical loading of the measured and measurement circuits
05. Air flow over the test samples
06. Instrument resolution
07. Procedures used for conditioning and to prepare samples for test.

The accuracy method is the traditional approach to handling measurement uncertainty in the electro-technical sector. It allows the measured result to be directly compared to the test limit to determine conformance. It provides valid criteria for pass/fail decisions, while saving time and costs, for not having to define the measurement uncertainty according to the GUM¹, which defines highly theoretical procedures which are appropriate for calibrations and sometimes also testing but may prove unnecessarily complicated for manufacturers unless they are manufacturing measuring instruments with high requirements on measurement uncertainty.

¹ Guide to the expression of uncertainty in measurement (GUM) [12]

3.5 Appendix 5 – Compilation of the LVD technical documentation

According to clause 6 of the LVD [1], manufacturers shall draw up the technical documentation referred to in Annex III (of the LVD [1]) and carry out the conformity assessment procedure referred to in Annex III or have it carried out on their behalf.

This technical documentation includes:

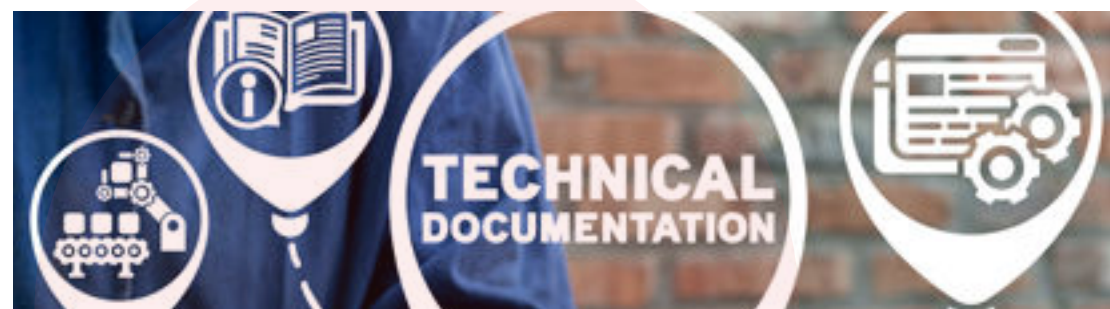
- a.** a general description of the electrical equipment.
- b.** conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.
- c.** descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the electrical equipment.
- 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 or international or national standards referred to in Articles 13 and 14 and, where those harmonised standards or international or national standards

have not been applied, descriptions of the solutions adopted to meet the safety objectives of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or international or national standards referred to in Articles 13 and 14, the technical documentation should specify the parts which have been applied.

- e.** results of design calculations made, examinations carried out, etc.; and
- f.** test reports.

The test report as discussed in the previous appendix is the most important part of the technical documentation. A market surveillance authority may ask to have it made available. Some manufacturers publish their test reports on their websites.

Although it is stated in Annex III of the LVD [1] that the manufacturer must make a risk assessment for his product, it does not need to be part of the technical documentation.



3.6 Appendix 6 – Declaration of conformity and conformity assessment marking

If required by the applicable legislation of the market where the product is intended to be placed, the manufacturer shall affix the requested conformity assessment marking to each individual electrical equipment that satisfies the applicable requirements of the LVD [1] (N.B.: the affixing of the CE marking is mandatory if the product is also intended to be placed on the EU single market). The manufacturer shall draw up a written declaration of conformity for a product model and keep it together with the technical documentation at the disposal of the local market surveillance authorities upon request for 10 years after the electrical equipment has been placed on the market. This means the last equipment of that model placed on the

market. The declaration of conformity shall identify the electrical equipment for which it has been drawn up.

It is good practice for manufacturers to put this declaration of conformity on their website. The information to be provided on the declaration of conformity is described in Annex IV of the LVD [1].

The declaration of conformity should be signed by a representative of the company who has obtained the required authority of his management to do so. In practice it is usually declared and signed by the quality manager of the company.

3.7 Appendix 7 – Internal production control

The manufacturer should take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured electrical equipment with the technical documentation referred to in point 2.5. of this guide and with the requirements of the LVD [1] that apply to it (Annex III (3) of the LVD [1]).

The method to ensure that each equipment is in conformity with the LVD [1] is to make routine tests. These tests are performed on each equipment at the end of the production line. In most cases, the harmonised standards define these routine tests. For instance, the

EN 61010-1, standard in the annex F requires the following routine tests to be performed:

- 01.** A protective earth continuity test (to ensure that all relevant metal parts are adequately earthed)
- 02.** An electric strength test between active parts (mains parts) and accessible conductive parts (to ensure that there is no insulation fault)

If the routine tests are not specified in the applicable harmonised standard, the EN 62911², standard may be used.

² EN 62911 defines routine electrical safety test procedures for use during or after manufacturing of complete equipment, sub-assemblies or components, complying with EN 60065, EN 60950-1 or EN 62368-1 and powered by an a.c. mains supply or d.c. mains supply, to detect manufacturing failures and unacceptable tolerances in manufacturing and materials. All the tests defined in this standard do not necessarily have to be performed at the end product manufacturing location.

3.8 Appendix 8 – Obligations of the manufacturer in the market surveillance process

The LVD [1] refers to Article 15(3) and Articles 16 – 29 of Regulation (EC) No 765/2008³ for market surveillance. Art. 16 – 29 describe the set-up of a market surveillance system from a viewpoint of the market surveillance authority and other regulatory authorities or parties, for example the Customs Authorities. It includes also the serious risk requirements.

More specific market surveillance requirements are in Art. 19 – 22 of the LVD [1] such as what is meant by “formal non-compliance”, what the administrative requirements are, etc., for example whether the conformity marking has not been fixed to the equipment. This article allows for market surveillance authorities to take quick action without testing.

The obligations of the manufacturer, its authorised representatives, importers and distributors are described in Chapter 2 of the LVD [1].

Furthermore, Chapter 4 of the LVD [1] describes the actions that may be taken by the market surveillance authorities and that may have an impact on the economic operators concerning electrical equipment presenting a risk on the local market.

The tasks of the manufacturer related to market surveillance of their products can be formalised by incorporating these tasks into a procedure, which can be part of the quality management system of the manufacturer.

Related to sample testing of the equipment, the ISO 2859-1⁴ [13] should be used.

The maximum acceptance quality level is proposed to be 10 % for safety critical parameters in the equipment.

3.9 EU Market Surveillance Actions

The reports of cross-border LVD [1] market surveillance actions are available within the ADCO LVD site of the European Commission. These reports allow manufacturers to understand the scope and depth of these market surveillance actions.

https://single-market-economy.ec.europa.eu/single-market/goods/building-blocks/market-surveillance/organisation/adcos_en

³ This has been replaced by Regulation (EU) 2019/1020.

⁴ ISO 2859-1, Sampling procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection

4. EMCD conformity assessment flowchart



It should be emphasized that the use of the terms “apparatus” and “equipment”, which refers to apparatus and fixed installations, follow the definitions in the EMCD [2].

Where this Directive regulates apparatus, it should apply to finished apparatus placed on the market. Certain components or sub-assemblies should, under certain conditions, be considered to be apparatus if they are made available to the end-user.

These EU EMCD Guidelines [4] are limited to EMC conformity assessment for apparatuses that are finished appliances like LED lamps, audio & video and IT equipment and the like, so in fact in the lighting industry area.

Indeed, treatment of EMC conformity assessment of industrial products would bring us to very specific EMC standards and related EMC test methods.

While EMC conformity assessment guidance has been well elaborated in the EU EMC guide of 2018 [4], the guidance provided in this guideline focuses on the pre-compliance part of the EMC conformity assessments. An important justification to take this approach is the cost aspect, because harmonised EMC product standards require the EMC tests or measurements to be performed in a controlled electromagnetic environment, such as anechoic chambers. These facilities are expensive and their operation requires specific testing knowledge.

It is better to focus on the pre-compliance part of an EMC conformity assessment, i.e. the time when the manufacturer is developing his equipment or the time when he is redesigning his equipment considering the results of the EMC compliance tests/measurements.

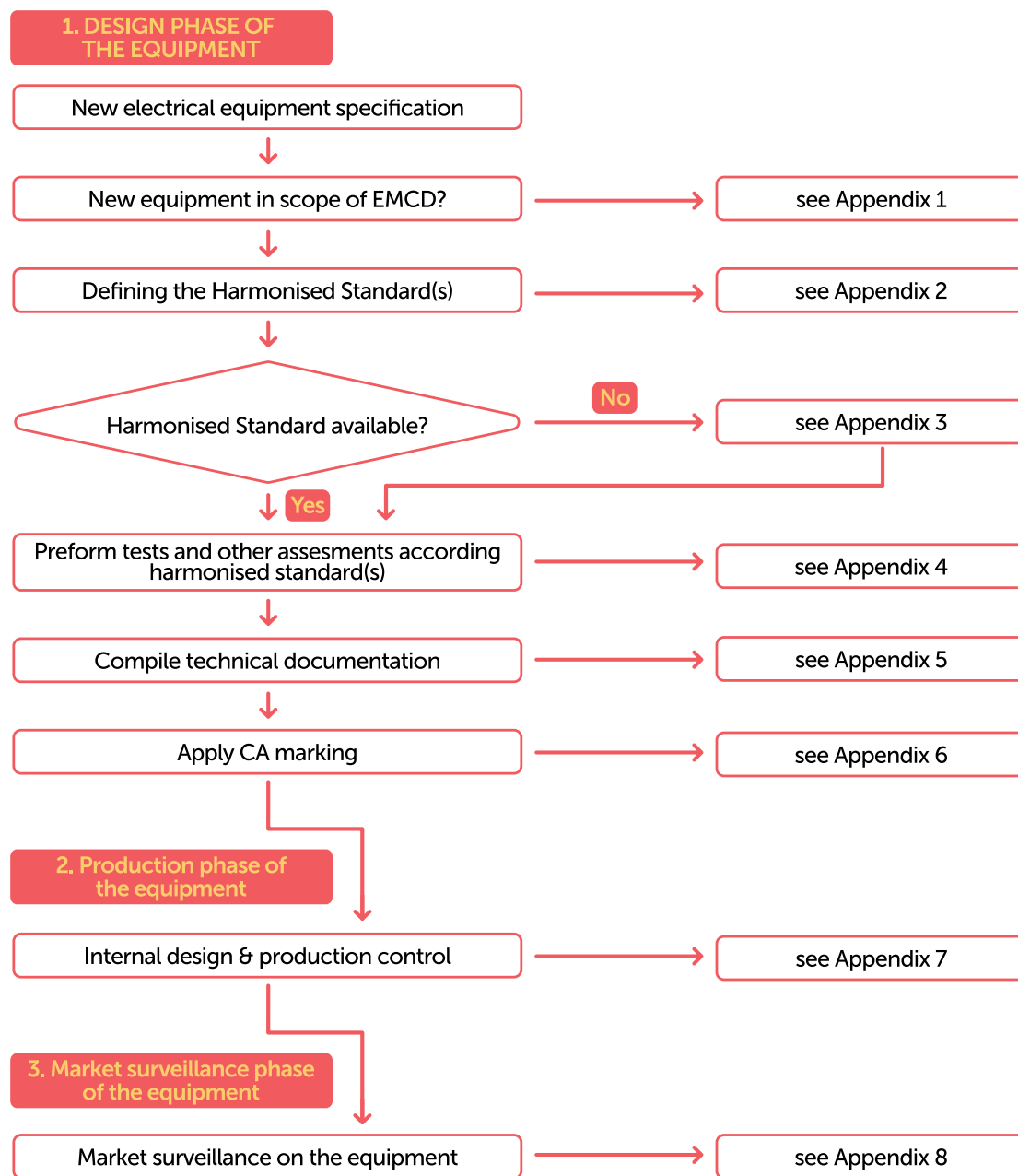


Fig. 2: overall EMCD conformity assessment for finished appliances

4.1 Appendix 1 – Equipment within the scope of the EMCD [2] and exclusions

The EMCD [2] applies to a vast range of equipment encompassing electrical and electronic appliances, systems and installations.

The main objective of the EMCD [2] is to guarantee the free movement of equipment and to create an acceptable electromagnetic environment whilst ensuring that equipment will function as intended in that environment.

The EMCD [2] only covers 2 functional aspects of an equipment operating in its electromagnetic environment, namely:

- 01.** That the electromagnetic disturbance generated by the equipment does not exceed the level above which radio and telecommunication equipment or other equipment cannot operate as intended.
- 02.** That the equipment has a level of immunity to the electromagnetic disturbance to be expected in its intended use which allows it to operate without unacceptable degradation of its intended use.

The above 2 statements are from Annex 1 of the EMCD [1], the essential requirements.

The EMCD [2] is not a “totally harmonised safety Directive” like the LVD [1]. It should be noted that other directives (like the LVD [1]) may require higher requirements for EMC phenomena in order to satisfy their specific safety provisions, for example for functional safety requirements.

However, there are some limitations to its scope.

Exclusions to the EMCD [2]

The list of excluded equipment is clearly stated in Clause 1.4 of the EU EMCD guide [4]. The reasons for the exemptions for some electrical equipment, are that they are covered by other more specific EU acquis. For instance: radio equipment (covered by the radio equipment directive – RED), medical equipment, equipment used in vehicles or ships, etc. Some equipment is partially excluded from the EMCD [2], for example, for measuring instruments the immunity aspect is covered in the Measuring Instrument Directive 2014/32/EU. However, the emission aspects for these measuring instruments are covered by the EMCD [2].

Other electrical equipment is excluded because of different reasons for example, equipment without active electronic circuits.

In annex 4 of the EU EMCD guide [4], the application of the EMCD [2] with reference to the LVD [1] and the RED, is further discussed.

4.2 Appendix 2 – Defining the harmonised standards for the equipment

Similar to what was stated for the LVD [1], the use of a harmonised standard by a manufacturer will provide presumption of conformity with the corresponding essential requirements of the EMCD [4]. This is a very important and far-reaching statement, which provides among other benefits, legal certainty to the manufacturer. A harmonised standard published in the OJ has the recognition that its content covers the essential requirements (Annex 1 of 2014/30/EU) of the EMCD [2].

As stated previously for the LVD [1], according to the regulation (EU) No. 1025/2012 [6] on European standardisation, it is required that each harmonised EMC standard for products clearly states the relation of the clauses of the

standard with the essential requirements of the EMCD [2].

In practice this means that every harmonised standard needs an annex ZZ at the end of the EN harmonised standard, in which the relation between the 2 essential requirements of the EMCD [2] and the clauses of the harmonised standard are listed (see fig. 3 below). To date, the HAS consultants' system has not introduced an EMC risk assessment method like the Guide 32 of CENELEC [11] for LVD [1]. There is however a list of electromagnetic phenomena in Annex 3 of the EU EMCD guide [4]. The manufacturer may use this list for performing his EMC risk assessment of his equipment.

Annex ZZB (informative)

Relationship between this European standard and the essential requirements of Directive 2014/30/EU [2014 OJ L96] aimed to be covered

This European standard has been prepared under the European Commission standardisation request C(2016) 7641 final of 30.11.2016, ('M/552'), as regards harmonised standards in support of Directive 2014/30/EU relating to electromagnetic compatibility, to provide one voluntary means of conforming to essential requirements of 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 [2014 OJ L96].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZZB.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive, and associated EFTA regulations.

Table ZZB.1 - Correspondence between this European standard and the Essential Requirements set out in Directive 2014/30/EU [2014 OJ L96]

Essential requirements of Directive 2014/30/EU	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
Annex I. 1(a) (electromagnetic disturbances)	2, 8.3.1, 8.3.3, 9.4.1, 9.4.3	
Annex I. 1(b) (electromagnetic immunity)	2, 8.3.1, 8.3.2, 9.4.1, 9.4.2	

Figure 3: the annex ZZ (from EN IEC 60947-6-2 partly shown)

4.3 Appendix 3 – When harmonised standards are not available for the equipment

Although there are more than 200 EMC harmonised standards [15] published in the OJ, there are still some which are not harmonised. Manufacturers may use these non-harmonised standards in the design of their products but cannot claim through their use the presumption of conformity with the EMCD [2].

Also, for some equipment there are no harmonised standards or even IEC standards. For these situations, it will be more difficult for the manufacturer to prove compliance with the essential requirements of the EMCD [2].

A method which is normally used in the absence of harmonised standards or when other standards are used, is that the manufacturer seeks for a harmonised standard for an electrical equipment that has similar characteristics and risks as the equipment for which he/she wants compliance with the EMCD [2]. The scope of the candidate harmonised standard should be read for that purpose.

Consequently, when there is similarity, the manufacturer shall perform a risk assessment on the equipment according to the electromagnetic phenomena list of Annex 3 of the EU EMC guide [4] to find out which EMC risks are not covered if the similar standard is used. The manufacturer may also contact the CENELEC TC (Technical Committee) responsible for that similar

standard and ask them to supply the risk assessment document.

For those electromagnetic phenomena which are not covered by this similar standard, the manufacturer shall provide an EMC conformity assessment. Once the EMC conformity assessment is completed and the manufacturer has identified the remaining electromagnetic phenomena not covered by the similar standard, the manufacturer shall perform tests for compliance of these electromagnetic phenomena with the EMCD [2] or have tests performed by an external laboratory.

For some tests like for low frequency immunity phenomena, it may be possible for the manufacturer to use a theoretical analysis, for example, using a simulation with SPICE⁵ of the mains input circuit to ensure that this circuit is not affected by the surge test of IEC 61000-4-5.

Harmonised standards provide a recognised methodology to demonstrate compliance with the essential requirements and are usually the preferred way to demonstrate compliance. The manufacturer may ask a third party to perform the EMC conformity assessment in whole or in part, but the manufacturer is and remains fully responsible for the compliance of his apparatus with the provisions of the Directive.

⁵ A free circuit simulation software like LTSPICE may be used to perform this simulation.

Which harmonised standards to use?

Useful practical information on the selection of the appropriate CENELEC standards may be found in the CENELEC Guide 25, Guide on the use of EMC standards for the implementation of the EMC Directive to apparatus, [10] which is available on the CENELEC website. The CENELEC Guide 24 [9], also available on the same website, explains the general structure of the EMC standardisation and the respective roles of EMC standards, e.g. basic standards, generic and product family standards. It should be noted that these 2 guides are currently under review and will be integrated into a single guide.

Families of products	Standards covering the protection EMC requirements			
	Emission			Immunity
	Harmonics (see Note 1)	Voltage fluctuations (see Note 1)	Radio-interference	(All aspects)
Household appliances and portable tools (motor-driven such as vacuum cleaners, washing machines etc; heating and cooking appliances, etc.)	EN 61000-3-2 or EN 61000-3-12	EN 61000-3-3 or EN 61000-3-11	EN 55014-1 (2)	EN 55014-2
Lighting equipment	EN 61000-3-2 or EN 61000-3-12	EN 61000-3-3 or EN 61000-3-11	EN 55015 (8)	EN 61547
TV receivers and audio equipment	EN 61000-3-2 or EN 61000-3-12	EN 61000-3-3 or EN 61000-3-11	EN 55013	EN 55020
Professional audio, video and entertainment lighting control equipment	EN 55103-1 (refers to EN 61000-3-2)	EN 55103-1 (refers to EN 61000-3-3)	EN 55103-1	EN 55103-2
Information Technology (IT) equipment	EN 61000-3-2 or EN 61000-3-12	EN 61000-3-3 or EN 61000-3-11	EN 55022	EN 55024
Mains signalling equipment (7)	-	-	EN 50065-1	EN 50065-2-1 EN 50065-2-2 EN 50065-2-3
ISM equipment	EN 61000-3-2 or EN 61000-3-12	EN 61000-3-3 or EN 61000-3-11	EN 55011	EN 61000-6-2
Industrial equipment in general	- (3)	- (3)	EN 61000-6-4	EN 61000-6-2

Figure 4: table 1 of CENELEC guide 25 list the EMC harmonised standards which are applicable to different kind of equipment.

4.4 Appendix 4 – Performance of EMC tests and measurements

If the harmonised standards route is followed, the manufacturer shall perform or have performed by an external laboratory, the tests and measurements according to the relevant harmonised standard(s). The EMC harmonised standards [15] refer to EMC basic standards, for example, the IEC 61000-4 series for immunity and CISPR 16 series for emission. These EMC basic standards incorporate basic test set-ups and the measurement uncertainties. The determination of these measurement uncertainties requires specific test environments, for example, the use of anechoic chambers and specific knowledge. This is the reason why most manufacturers (in most cases the SMEs) perform EMC tests in external accredited EMC laboratories.

Pre-compliance EMC test and measurements

While accredited EMC tests and measurements are expensive, the manufacturer will need pre-compliance tests and measurements especially in the design phase of the equipment. This pre-compliance equipment and facilities are cheaper in purchase with a downside that they are less accurate, i.e. the measurement uncertainty budgets are bigger. This is not an issue because the manufacturer then performs tests using a higher test level and uses a lower measurement level, to

compensate for the higher uncertainty levels.

Examples of pre-compliance test methods

Radiated Emissions

Because radiated emissions are usually the most frequent test failure, most of the pre-compliance investment should be focused on this test.

While a fully compliant anechoic (absorber lined) test chamber can be prohibitively high in cost, there are currently EMC test chambers on the market that provide for example, absorber materials which are less expensive while providing an acceptable tolerance on site attenuation when installed in a small chamber (1 – 3 meter antenna test distance).

This pre-compliance anechoic chamber can be validated with a comb-generator⁶ referred to the site attenuation of a full compliance anechoic chamber.

Conducted emissions

Conducted emissions on the mains side of an equipment in harmonised standards are measured using a LISN (Line Impedance Stabilisation Network). A simpler and less costly method is to use a self-made current probe.

⁶ A comb generator is a signal generator that produces multiple harmonics of its input signal. The appearance of the output at the spectrum analyzer screen, resembling teeth of a comb, gave the device its name

This current probe measurement may be compared with a comb-generator in an accredited lab to the method used with the LISN.

List of pre-compliance test equipment other than those mentioned above

Radiated & Conducted Emissions

- 01.** Calibrated EMI antenna (30 to 1000 MHz, min.) Several manufacturers make calibrated EMI antennas. However, affordable, compact, troubleshooting antennas (limited calibration) based on PC board designs are available too.
- 02.** Non-metallic tripod that can hold the antenna at 1m, or more, in height (see antenna manufacturers).
- 03.** Basic spectrum analyser that covers up to at least 1 GHz. Portable spe-

ctrum analysers are also a good choice. Good quality second-hand spectrum analysers are also regularly published on websites dedicated to second-hand equipment.

- 04.** Non-metallic table for EUT (equipment under test) could be a manual turntable or even a roll-around cart.
- 05.** Ideally a ground plane, but most pre-compliance setups just use the floor.
- 06.** Line Impedance Stabilization Network (LISN) for conducted emissions. These come in DC and AC models.

The manufacturers are responsible for choosing the tests requested through harmonised standards or through relevant risk assessment.



Figure 7: examples of radiated and conducted emission measurement equipment

4.5 Appendix 5 – Compilation of the EMCD [2] technical documentation

According to clause 7 (2) of the EMCD [2], manufacturers shall draw up the technical documentation referred to in Annex II (internal production control by the manufacturer) or Annex III (involvement of a notified body) of the EMCD [2] and carry out the conformity assessment procedure referred to in Art. 14 or have it carried out.

This technical documentation includes:

- 01.** an identification of the product covered by the technical documentation. This identification should allow an unambiguous link between the technical documentation, the EU Declaration of Conformity and the product.
- 02.** a general description of the apparatus. The amount of information required will depend on the complexity of the apparatus; simple apparatus may be fully defined in one line, whereas more complex apparatus may need a complete description (a picture may be included).
- 03.** conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc. See Section 4.3 "Technical documentation" in the Blue Guide [7] 4th paragraph.
- 04.** descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the apparatus.
- 05.** if harmonised standards have been applied then evidence of conformity is required. As a minimum this will be a dated list of the European harmonised

standards applied and the results obtained from their application.

- 06.** if harmonised standards have not been applied or have been applied only in part then a description of the steps taken to meet the essential requirements – an EMC conformity assessment described in Annex II of the Directive must be included. In that event the technical documentation shall specify which parts of the harmonised standard have been applied. A list of other technical specifications used shall be included where harmonised standards are not used. The documentation includes test reports, design calculations made, examinations carried out etc.
- 07.** if a manufacturer is using the procedure of Annex III of the EMCD [2], then the EU-type examination certificate issued by a Notified Body shall be included when exporting to the EU. If a similar procedure is required by the local authorities or the authorities of the market on which the product will be put on the market then the manufacturer should follow that procedure.

The test report as discussed in the previous appendix is the most important part of the technical documentation. A market surveillance authority may ask for it to be made available. Some manufacturers publish their test reports on their website.

Although it is stated in Annex II and III of the EMCD that the manufacturer has to develop a risk assessment for his product, it does not need to be part of the technical documentation.



4.6 Appendix 6 – Declaration of conformity and conformity assessment marking

Similar to the requirements of the LVD [1], the manufacturer shall affix, when required, the conformity assessment marking to each individual electrical equipment that satisfies the applicable requirements of the EMCD [2]. The manufacturer shall draw up a written declaration of conformity for a product model and keep it together with the technical documentation at the disposal of the local market surveillance authorities for 10 years after the electrical equipment has been placed on the market. This means the last equipment of that model placed on the market. The declaration of conformity shall identify the electrical equipment for which it has been drawn up. If more than one directive applies to a product, compliance with all of the applicable directives can be stated in the same declaration of conformity. This is a general rule. A copy of the declaration of conformity shall be made available to the relevant market surveillance authorities upon request. It is good practice for manufacturers to put this declaration of conformity on their web site.

The information to be provided in the declaration of conformity is described in Annex IV of the EMCD [2].

The declaration of conformity should be signed by a representative of the company who has obtained the required authority of his management to do so. In practice, it is usually declared and signed by the quality manager of the company.

4.7 Appendix 7 – Internal production control

Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Directive. Changes in apparatus design or characteristics and changes in the harmonised standards or in other technical specifications by reference to

which conformity of the apparatus is declared shall be adequately taken into account (art. 7 (4) of the EMCD [2]).

Routine tests (as for the LVD [1]) have not been foreseen in the EMCD [2].

4.8 Appendix 8 – Obligations of the manufacturer in the market surveillance process

Similar to the LVD [1], the EMCD [2] refers to Article 15(3) and Articles 16 – 29 of Regulation (EC) No 765/2008 on accreditation and market surveillance (Art. 37 of the EMCD). Art. 16 – 29 describe the set-up of a market surveillance system from a viewpoint of the market surveillance authority and other regulatory instances or parties such as the Customs Authorities. It also includes the serious risk requirements.

More specific market surveillance requirements are in Art. 7 (obligations for manufacturers), Art. 9 (obligations for importers), Art. 12 (identification of economic operators) and

Art. 38 (procedure for apparatus presenting an EMC risk at national level).

The above-mentioned tasks of the manufacturer related to market surveillance of their products can be formalised by incorporating these tasks into a procedure, which can be part of the quality management system of the manufacturer.

Related to sample testing of the equipment, the ISO 2859-1⁷ [13] should be used.

The maximum acceptance quality level is proposed to be 10 % for EMC critical parameters in the equipment.

4.9 EU market surveillance actions

The reports of cross-border EMC market surveillance actions are available within the ADCO EMC site of the European Commission. These reports allow manufacturers to understand the scope and depth of these market surveillance actions.

https://single-market-economy.ec.europa.eu/single-market/goods/building-blocks/market-surveillance/organisation/adcos_en

⁷ ISO 2859-1, Sampling procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection

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[11] CENELEC Guide 32, Guidelines for Safety Related Risk Assessment and Risk Reduction for Low Voltage Equipment

https://boss.cenelec.eu/media/Guides/CLC/32_cenelecguide32.pdf

[12] GUM: Guide to the Expression of Uncertainty in Measurement

<https://www.bipm.org/en/committees/jc/jcgm/publications>

[13] ISO 2859-1, Sampling procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection

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<https://ec.europa.eu/docsroom/documents/53895>

[15] Summary list of EMCD harmonised standards

<https://ec.europa.eu/docsroom/documents/51314>

[16] JCGM 106, Evaluation of measurement data – the role of measurement uncertainty in conformity assessment

https://www.bipm.org/documents/20126/2071204/JCGM_106_2012_E.pdf/fe9537d2-e7d7-e146-5abb-2649c3450b25

Published by:

Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH

Registered offices:

Bonn and Eschborn, Germany

Project:

Open Regional Fund for Southeast Europe - Foreign Trade

Giz Office Sarajevo

Zmaja od Bosne 7- 7a, Importantne Centar 3/IV

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Design/Layout: BORAM

Photo credits @GIZ, @Shutterstock

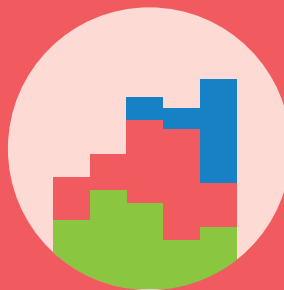
The programme is co-funded by the European Union and the German Federal Ministry for Economic Cooperation and Development (BMZ).

GIZ is responsible for the content of this publication.

As at: 2023, Sarajevo

Guidelines for electrical products

Implementation of Low Voltage (2014/30/EU) and
Electromagnetic Compatibility (2014/35/EU) Directives



This publication was produced with the financial support of the European Union and the German Federal Ministry for Economic Cooperation and Development (BMZ). Its contents are the sole responsibility of GIZ and do not necessarily reflect the views of the EU or the Federal Ministry for Economic Cooperation and Development (BMZ).



Co-funded by
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