

# Conformity assessment procedures for the Electrical Safety scheme

		_	_
RD	031	Issue	ი7

This guide describes the conformity assessment procedures and requirements for products under the scope of the Low Voltage Directive when placing these products on the European market

No rights may be derived from the text of this document. Copyright © 2022



# **Revision record sheet**

NOTE: The person who initiated the document or modified the document is responsible for maintaining this record sheet (in case of use please remove revision information)

Revision	Section number	Page number	Date	Remark(s)	issued by
4	-	2	12-09-2013	Revision record sheet added	KEB
4	-	-	12-09-2013	Change of document name	KEB
5	1.1	4	15-08-2016	Modified paragraph About Telefication	EB
	4.5	9	15-08-2016	Modified paragraph Termination (expiration), reduction, suspension and withdrawal of Certificates	ЕВ
	Abbreviations etc.	Annex A	15-08-2016	control on EN 45011 and EN 45012; replace by "ISO/IEC 17065" resp. "ISO/IEC 17021-1"	EB
	Annex E	21	16-08-2016	Changed Phone number	EB
	Annex D	20	17-08-2016	Added RQ_160	EB
6	1.1	4	17-09-2019	Information added "This scheme does not fall under the NEN-EN-ISO/IEC 17065 accreditation"	AG
7	Complete	All	23-05-2022	Logo / name Telefication replaced by Kiwa and where applicable accreditation / website / No. body number reference have been updated.	AG

Issued/modified by : Axel Gase

Function : Quality Assurance Manager

Revision : 7

Date : 23-05-2022

Verified by : Willem Jan Jong

Function : Manager Product Certification

Date : 23-05-2022

Released by : Axel Gase

Function : Quality Assurance Manager

Date of release : 23-05-2022



# Contents

REVI	ION RECORD SHEET	2
1 IN	TRODUCTION	4
1.1	ABOUT KIWA	
1.1	ABOUT THIS DOCUMENT	
2 E	ROPEAN REGULATIONS	
2.1	THE NEW APPROACH	
2.2	THE SCOPE OF THE LVD	
2.3	THE GLOBAL APPROACH	5
3 C	ONFORMITY ASSESSMENT PROCEDURES	7
3.1	THE VARIOUS CONFORMITY ASSESSMENT PROCEDURES	7
4 T	HE APPLICATION	8
4.1	REQUIRED DOCUMENTATION	8
4.2	PRODUCT VARIANTS	8
4.3	GENERAL REQUIREMENTS	9
	.1 The Declaration of Conformity	
	.2 The technical file	
	.3 The affixing of markings	
4.5	TERMINATION (EXPIRATION), REDUCTION, SUSPENSION AND WITHDRAWAL OF CERTIFICATES	
	.1 Emergency procedure	
5 M	ODIFICATIONS FOLLOWING CERTIFICATION	10
5.1	TYPES OF MODIFICATIONS	
5.2	CHANGES TO THE DETAILS OF THE CERTIFICATE-HOLDER	
5.3	CHANGE OF CERTIFICATE-HOLDER	
5.4	ALTERATION/ADDITION OF A MODEL DESIGNATION AND/OR TRADEMARK	
5.5	ADDITION OF NEW PRODUCT VARIANTS	
5.6 5.7	MODIFICATION OF PRODUCT HARDWARE/SOFTWARE	
	MODIFICATIONS NOT AFFECTING THE ESSENTIAL REQUIREMENTS	
6 T	E TECHNICAL FILE	
6.1	Introduction	
6.2	PURPOSE OF THE TECHNICAL FILE	
6.3	FORM AND CONTENT OF THE TECHNICAL FILE	
6.4	AVAILABILITY OF THE TECHNICAL FILE	12
7 M	ARKINGS	
7.1	THE CE MARKING	13
ANNI	X A ABBREVIATIONS AND PARAPHRASES	14
ANNI	X B THE DECLARATION OF CONFORMITY	17
	CONTENT OF THE DECLARATION	
B.1 B.2	Drawing up a declaration	
ANNI		
TITIT		
ANNI	X D FORMS AND DOCUMENTS	20
ANNI	K E ADDITIONAL INFORMATION	21



# 1 Introduction

### 1.1 About Kiwa

Kiwa Nederland B.V. (unit Wireless & EMC), hereinafter to be referred to as Kiwa) is a third party test laboratory and third party certification body. The Dutch Council for Accreditation (Raad voor Accreditatie: RvA) has accredited the unit wireless & EMC (legal entity of Kiwa NL B.V.) to ISO/IEC 17025 (laboratory) and NEN-EN-ISO/IEC 17065 (product certification).

More information about Kiwa Nederland B.V. (unit Wireless & EMC), is available in RD\_0063.

### 1.2 About this document

This document lays down the procedure for manufacturers and importers who want to place products under the scope of the Low Voltage Directive on the market of the European Union, including Iceland and Norway.

This document states the procedures for operating as an assessment body in accordance with Article 8(2) or Article 9 of the European Directive 2006/95/EC (codified version of European Directive 73/23/EEC, further referred to as LVD). Such an assessment body must have been notified to the European Commission by The Netherlands in accordance with Article 11(b) of the LVD.

This document establishes a link between the requirements of the LVD and the issue of a report in accordance with Article 8(2) and/or the issue of an opinion in accordance with Article 9 of the LVD.

These conformity assessment procedures are derived from the European Low Voltage Directive 2006/95/EC (LVD). The LVD came fully into force on 16 January 2007 (20 days after 27 December 2006).



# 2 European regulations

The creation of an open market in Europe was an important step towards free trade in goods and products within the European Union. However, since the Member States of the European Union have different laws, statutory procedures and requirements for the marketing of products, these barriers to trade need to be eliminated. To this end, the European Council adopted a resolution in 1985 on a New Approach to technical harmonisation and standards, better known as **The New Approach**.

# 2.1 The New Approach

The fundamental principles of the New Approach include the following:

- Directives will be introduced to harmonise the laws of the Member States;
- Harmonisation will be confined to the formulation of 'essential requirements'. These are general criteria, which products must meet if they are placed on the European market. They mainly concern safety, health and the environment;
- On the basis of the essential requirements, technical standards will be developed by designated standardization organisations. Following adoption by the European Commission, these standards will acquire the status of *harmonised standards*. These standards are necessary to provide manufacturers with a clear picture of the requirements that products must meet;
- The manufacturer is formally not obliged to apply harmonised standards; rather they are a way of showing that the essential requirements are met. In the practice of the LVD the application of harmonised standards is de facto obliged. If no harmonised standards exist other standards may be used or assessment may be performed directly to the essential requirements;
- If the manufacturer does apply harmonised standards, it will be assumed that the product conforms to the essential requirements. This is known as the 'presumption of conformity'.

The New Approach has led to the adoption of European Directives based on these principles. These Directives are therefore often called *new-approach Directives*. Most of them relate to a specific category of products, e.g. toys, medical appliances, telecommunications terminal equipment, and construction products and some of them relate to matters such as safety and electromagnetic compatibility.

In 2006 the following Directive laid down the requirements for the (electrical) safety of products:

• Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits.

This Directive lays down the principal elements of safety objectives for products as defined in the scope. This Directive is also know as the **Low Voltage Directive or LVD**.

The Directive as mentioned above is the codified version of Directive 73/23/EEC of 19 February 1973.

# 2.2 The scope of the LVD

The scope of the LVD is defined by Article 1 of the LVD.

# 2.3 The Global Approach

To create a consistent system for the assessment of products, the European Council adopted a resolution<sup>2</sup> on 21 December 1989 on the approach to conformity assessment. This resolution is better known as the **Global** 

Council Resolution 85/C 136/01 on a new approach to technical harmonization and standards of 7 May 1985 (OJ No. C 136, 4.6.1985, p.1).

<sup>&</sup>lt;sup>2</sup> OJ No. C 10, 16.1.1990, p. 1.



**Approach**<sup>3</sup>. The principles of the Global Approach are described in detail in Council Decision 93/465/EEC of 22 July 1993<sup>4</sup> (replacing Council Decision 90/683/EEC of 13 December 1990).

The Global Approach describes seven procedures for the assessment of products. Each procedure comprises both the design phase and production phase of a product. The seven procedures differ in nature and are applied according to the potential risk associated with a product. For instance, pacemakers have to satisfy much more stringent assessment requirements than toy trains.

Depending on the risk associated with a particular product, Directives specify in which cases the manufacturer himself may determine whether the products conform to the essential requirements in the Directive(s) and in which cases this has to be assessed by a third party, a *Notified Body*, by means of certification and/or have to be tested by a *Designated Laboratory*.

The LVD was adopted before the Global Approach. As a consequence of that the principles of the Global Approach are not followed in all details by the LVD.

Council Decision 93/465/EEC concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking of 22 July 1993 (OJ No. L 220, 30.8.1993, pp. 23-39).



# 3 Conformity assessment procedures

# 3.1 The various conformity assessment procedures

The LVD allows a body to issue a technical report (in the form of a test report and/or certificate) declaring electrical equipment, in the scope of Article 1 of the LVD and outside of the scope of Annex II of the LVD, which is placed on the market by a manufacturer, importer or a responsible person, to be in conformity with the requirements of Annex 1 of the LVD.

This document describes the procedures applied by Kiwa in order to issue a technical report or opinion as an assessment body in accordance with Article 8(2) or Article 9 of the LVD for products in the scope of Article 1 of the LVD. This document is not valid for products as listed in Annex II of the LVD.

Formally it is always the manufacturer, importer or a responsible person who has the sole responsibility for the products to be in conformity with Annex 1 of the LVD. However, the information in the Technical Construction File (TCF), as defined in Annex IV of the LVD, or the products themselves may be assessed by Kiwa as an assessment body for the purpose of issuing a technical report or opinion verifying that products comply with the principal elements of the safety objectives as listed in Annex 1 of the LVD.

To reduce the chance of difference of opinion between Kiwa engineers, who are entitled to review a TCF or issue an opinion.

Kiwa, operating as an assessment body in the context of the LVD, will accept any request for a TCF assessment, the issue of an opinion or testing products, wherever this request comes from, taking into account Kiwa's capabilities and work load.

Kiwa will limit the testing and/or requests for providing documentation to what is essential for the purpose of the assessment of conformity.

Where there are discrepancies between the text of this procedure and the LVD, the text of the LVD takes preference.

The technical report as issued by Kiwa shall be limited to the statement that the testing and other procedures carried out for the conformity assessment have been correctly performed, regardless of whether they were carried out by the manufacturer, by any other party, or by Kiwa as an assessment body.

Kiwa issues the technical report or opinion for the test and tasks as requested by the client and is only responsible for the assessment that it performs.



# 4 The application

# 4.1 Required documentation

The applicant shall provide the following information (in the case of a TCF assessment):

A full TCF in conformity with the requirements of Annex IV of the LVD must be submitted, including the description and identification of electrical equipment and including schematic diagrams, the description of any measurements, examinations and derived results supported by tables graphs, sketches and photographs as appropriate.

Note: The TCF shall be made available in either Dutch or English, with the exception of the user manual which must also be made available in the original form. If the TCF is presented in another language, it shall be translated in either Dutch or English. This translation must be supplied by the applicant and shall be the official version for assessment. A TCF may be provided in electronic form (preferably in PDF-file format).

- -Identification of the signatory empowered to bind the manufacturer or his authorized representative;
- -Product documentation normally supplied to the user;
- -List of items to be delivered to the user together with the electrical equipment;
- -The availability of the electrical equipment or if practical impossible the place where the electrical equipment is located and can be inspected by Kiwa engineers;
- -Any other information that is necessary to judge compliance with the requirements of the LVD.

#### Information on:

- -Items pertaining to products specifications and service requirements;
- -Serviceability (including "service maintenance", such as ease of access to serviceable items);
- -Fail safe characteristics;
- -Labelling, warnings, identification, traceability requirements, and instructions for commissioning, installations, use and maintenance as appropriate.

#### Information on safety aspects:

For cases where a safety problem can not be eliminated or minimized by "built-in" technology - including the use of appropriate guarding means - information on safety aspects shall be required to be given to persons involved (for example, installers, operators, users, service personnel and other third parties).

### Such information may include:

- -Instructions/markings to specify the procedure or electrical equipment to be used (prohibition or mandatory warning notices):
- -Instructions/marking regarding certain risks pertaining to normal use or reasonably foreseeable misuse (warning notices);
- -Instructions concerning the necessity of periodic maintenance or test.

Note: In principle, superfluous or unnecessary instructions/markings shall be avoided as they tend to decrease the value of those instructions/markings that are essential.

# 4.2 Product variants

A product may be marketed in different variations. Not all of these variations need to be assessed by Kiwa provided that the TCF clearly identifies each variant and clearly describes the variant(s) regarding its similarities and differences with the "main" product.



# 4.3 General requirements

This section describes 'The declaration of conformity', 'The technical file' and 'The affixing of marking' requirements that do apply to all aforementioned procedures.

# 4.4.1 The Declaration of Conformity

The manufacturer or importer<sup>5</sup> must draw up a *Declaration of conformity* for each product and subsequent model descriptions. This is a document in which the manufacturer or importer declares that the product in question complies with the principal elements of the safety objectives of the the LVD.

A model of the Declaration of Conformity (to type) is given in annex B.

#### 4.4.2 The technical file

The manufacturer must compile a technical file. The manufacturer or his authorised representative in the EEA should keep this file for at least 10 years after the last product has been manufactured. If the manufacturer is not established in the EEA and has not appointed a representative, the file must be kept by the person who has placed the product on the market. The file is primarily intended for inspections carried out by competent national government authorities. See also chapter *The Technical File*.

### 4.4.3 The affixing of markings

The LVD states that a CE marking, consisting of the initials CE, must be affixed to every product placed on the market of the EEA in accordance with all the provisions of all Directives which may be applicable to the product (see also the section 'Markings'). The initials CE only need to be affixed once, even in the case where several Directives apply.

# 4.5 Termination (expiration), reduction, suspension and withdrawal of Certificates

The certificates issued by Kiwa under ISO/IEC 17065 accreditation can get a change in their active status, as published on the Kiwa website, due to passing the expiry date, changes in the prerequisites for certification, when a non-conformity with the certification requirements is substantiated or when the client requests for changes. In RQ\_160 is defined for the related possibilities e.g. termination, suspension and reduction which action must be taken and how these actions have to be performed.

# 4.5.1 Emergency procedure

In case Kiwa is or has become aware of any serious safety risk that conflicts with the safety aspects of the LVD directive (Annex I), possibly caused by the certified equipment, Kiwa will immediately inform the certificate holder, the "Ministerie van Volksgezondheid, Welzijn en Sport" (VWS) and the "Voedsel en Warenauthoriteit" (VWA). Suspension or withdrawal of the certificate will follow when the suspection is evident.

In this case the importer is responsible for placing the product he has imported on the market.



# 5 Modifications following certification

# 5.1 Types of modifications

One or more of the following types of modifications may be involved.

#### Modifications of an administrative nature:

- changes to the details of the certificate-holder;
- change of certificate-holder;
- alteration/addition of a model designation and/or trademark.

#### Modifications of a technical nature:

- addition of new product variants;
- modification of product hardware/software:
- modifications not affecting the essential requirements.

# 5.2 Changes to the details of the certificate-holder

In this case, the certificate-holder remains the same, but there are changes, for example, to his address, fax number or telephone number. The certificate-holder should inform Kiwa of the changes as quickly as possible.

#### Comments

Modification does not affect the conformity. Kiwa will record the new details and send the applicant a confirmation. Certificates already issued remain unchanged.

# 5.3 Change of certificate-holder

The Certificate is drawn up in the name of the certificate-holder and is not transferable without the intervention of Kiwa. The name of the certificate-holder can, however, be changed, in which case the new certificate-holder automatically assumes all the responsibilities and obligations applicable under the issued Certificate in question.

#### Comments

The original holder of the certificate(s) must notify Kiwa in writing that the product should be transferred to the name of the new certificate-holder.<sup>6</sup> All the model designations and certificate numbers to which the transfer applies should be listed.

The new holder of the certificate(s) should inform Kiwa in writing that he is taking over the Certificate in question, and should list all the types and certificate numbers. He should also declare, and if necessary demonstrate, that he will fulfil all the responsibilities and obligations applicable under the original type-examination. The new certificate-holder draws up a Declaration of conformity for each type and sends a copy to Kiwa.

Kiwa will issue an Addition to the Certificate, in which the details of the new certificate-holder are stated.

# 5.4 Alteration/addition of a model designation and/or trademark

Alteration/addition of a model designation and/or trademark means that the hardware or software remains unchanged but the model designation and/or trademark under which the product is marketed is replaced by, or extended with, a new model designation.

#### Comments

In this case, the old model designation and/or trademark is replaced by a new one. It is also possible to market a product under both the old and new model designation and/or trademark. This applies to OEM products.

The approval-holder should notify Kiwa in writing of the alteration or addition of the model designation and/or trademark and declare that the new type(s) are identical to the already approved type. He should also indicate the old model designation and/or trademark and the approval/registration number and new model designation and/or trademark.

If the holder has been declared bankrupt, the receiver is the approval-holder.



An addition to the Certificate will be issued to the certificate-holder. All the relevant model designations and/or trademarks are listed in an annex.

# 5.5 Addition of new product variants

Addition of new product variants means that a new product variant is added to a type. The variants must all be based on the same design and may differ only in options, version, etc.

#### Comments

It is possible to place several product variants under one Certificate, each having its own model designation and/or trademark. However, the variants must form a product family, i.e. the variations in the products must be based on the same design. It must be possible to demonstrate that the variants belong to the same type, e.g. by means of a technical examination by a designated laboratory.

The manufacturer or importer draws up a new *Declaration of conformity* and sends a copy to Kiwa. Kiwa issues an Addition to the Certificate, in which the relevant model designations and/or trademarks are listed.

# 5.6 Modification of product hardware/software

This means that product hardware and/or software are modified in a way that affects, or may affect, conformity with the essential requirements.

#### Comments

The product must be subjected to (additional) tests by a laboratory. The additional test report(s) and all other altered documentation are submitted to Kiwa together with a modification application.

The manufacturer or importer draws up a new *Declaration of Conformity* and sends a copy to Kiwa. Kiwa issues an addition to the Certificate.

# 5.7 Modifications not affecting the essential requirements

Modifications of products that do not and cannot affect conformity with the essential requirements and do not involve changes to the details of the manufacturer, applicant and product description, do not need to be notified to Kiwa. However, if the modifications do effect the physical outlining of the product, adequate information for identification purposes needs to be provided to Kiwa.

If you are in any doubt, contact Kiwa.



# 6 The Technical File

### 6.1 Introduction

The LVD (and other EU Directives) requires the manufacturer to compile a Technical File. This file should contain all the data that can be used to show that the product conforms to the requirements of these Directives.

This section provides further information on the scope, content and form of the Technical File.

# 6.2 Purpose of the Technical File

The technical file plays a key role in the conformity assessment of a product. The manufacturer in co-operation with the approved bodies assesses the product and keeps the (test) data in a Technical File.

The file compiled by the manufacturer is primarily intended for the national authorities responsible for inspections. The national authorities have the right to require the manufacturer or importer to provide data showing that a product satisfies the requirements of a Directive. If the manufacturer or importer is unable or unwilling to supply this data, this provides sufficient grounds for questioning the 'presumption of conformity' with the Directives in question or for imposing sanctions.

#### 6.3 Form and content of the Technical File

The conformity assessment procedures are mainly intended to enable government bodies to make sure that the products placed on the market satisfy the statutory requirements. The manufacturer should be able to demonstrate by means of the technical file that the requirements are met.

The specific information that should be included in the technical file depends on the nature of the product and on the technical details needed to demonstrate that it conforms to either harmonised standards or the applicable essential requirements of the Directive. This should be indicated on a case-by-case basis, depending on the product.

It is recommended that the technical file shall be organized as follows:

- a first part containing a list of essential technical data necessary for the conformity assessment inspection, such as:
  - name and address of the manufacturer, and the model designation of the product;
  - the list of the harmonised standards applied by the manufacturer and/or the solutions he has adopted to satisfy the essential requirements;
  - a description of the product;
  - the manual, where applicable;
  - a general drawing of the product, where applicable;
  - records of complaints regarding the certified product(s).
- a second part, consisting of a complete file containing all the test reports, information on the quality manual, plans, descriptions of the products and processes, applied standards, etc.

# 6.4 Availability of the Technical File

The technical file should always be kept available to the national authorities for inspection purposes and to Kiwa. The obligation to have at least one Technical File available on the territory of the EEA commences when the product is placed on the market of the EEA, regardless of the product's geographical origin.

The obligation to keep the Technical File available rests with the manufacturer or his authorised representative established in the Community.

If the manufacturer is not established in the EEA and has no authorised representative in the EEA, the obligation falls on the person (dealer or importer) who places the product on the market of the EEA.

The file should be kept for at least ten years after the date on which the product was last manufactured.



# 7 Markings

All products that are within the scope of the LVD are subject to CE marking. The exact form and conditions are described in this section.

# 7.1 The CE marking

The affixing of a CE marking (Conformité Européenne) to products is an essential part of all *new-approach Directives*. If several Directives apply, the CE marking may, as a rule, be affixed only to products that comply with the conditions of all these Directives. When several Directives apply, the initials CE need to be affixed to the product only once.

The CE marking must satisfy the following criteria:

• The CE conformity marking shall consist of the initials "CE" taking the following form:

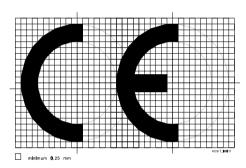


Figure 3: The initials CE.

- If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.
- The various components of the CE marking must have substantially the same vertical dimension, which
  may not be less than 5 mm.
- The CE marking shall be followed by the identification number of the body involved in the production control stage.

#### Additional information:

• The CE marking shall be accompanied by the name and identifying mark of the manufacturer, serial number (or batch number) and any other information which may be necessary to identify the manufacturer.



# Annex A Abbreviations and paraphrases

#### **Accredited laboratory**

A laboratory operating in accordance with a quality standard, in this case ISO/IEC 17025 and is assessed by a recognized Accreditation Board.

#### **Agentschap Telecom**

The Radio Communications Agency of the Ministry of Economic Affairs.

#### AoC

Attestation of Conformity (AoC).

#### **Approval Body**

A Notified Bodies, Designated Laboratories and Inspection Bodies are within the context of the LVD Approval Body.

#### Authorised representative

The person who, on the explicit (written) instructions of the manufacturer, acts on his behalf or for his account with respect to the obligations laid down in the Directive.

#### Rouwhesluit

The law in The Netherlands implementing the LVD is called Bouwbesluit.

#### **CE** marking

A mark consisting of one or more symbols, indicating that the product in question conforms to all the applicable Directives.

# **CE marking Directive**

This Directive (93/68/EEC) amends twelve Directives relating to the affixing of the CE marking, including the Low Voltage Directive.

#### Certificate-holder

The person to whom a Certificate of Conformity is granted.

#### CoC

Certificate of Conformity (CoC).

#### ιVΓ

Low Voltage Directive 2006/95/EC (LVD).

### Certification

A procedure whereby a third party gives written assurance that a product, process or service conforms to specified requirements (ISO/IEC Guide 2: 1991).

#### **Compulsory certification**

Certification required by a regulation or Directive before a product, process or service may be placed on the market.

### Compulsory conformity assessment

Conformity assessment relating to requirements laid down in regulations or Directives which must be undertaken before a product, process or service may be placed on the market.

#### **Conformity assessment**

Systematic examination of the extent to which a product, process or service satisfies further specified requirements (ISO/IEC Guide 2: 1991).

### **Declaration of Conformity**

The Declaration of Conformity is a document drawn up by the manufacturer, supplier or importer himself. It should indicate that the product concerned conforms to the standard(s) and Directive(s) to which the declaration refers. A model of the Declaration of conformity is described in standard EN45014, *General criteria for suppliers' declaration of conformity*.



When an Attestation of Conformity is part of the conformity assessment process, a Declaration of Conformity must be drawn up too. In this declaration one may refer to the Certificate of Conformity, instead of listing all applicable standards.

#### DoC

Declaration of Conformity (DoC).

#### **Dutch Council for Accreditation**

The Accreditation Body in The Netherlands in called Raad voor Accreditatie (in Dutch) or Dutch Council for Accreditation (in English).

#### EC type-examination procedure

A certification procedure whereby a Notified Body assesses the design, possibly by means of tests, of a representative specimen of the production envisaged.

#### EEA

The European Economic Area (EEA) comprises the member states of the European Union plus Norway, Iceland and Lichtenstein.

#### **FOTA**

European Organisation for Technical Approvals (EOTA).

#### FΤΔ

European Technical Approval (ETA).

#### FTAG

European Technical Approval Guideline (ETAG).

#### **ISO/IEC 17065**

The standard for accreditation of certification bodies is ISO/IEC 17065.

#### **Essential requirements**

These are general criteria which products must satisfy before they may be placed on the market of the EEA. The essential requirements relate mainly to safety, health and the environment.

#### **Family**

A type<sup>7</sup> may comprise several product variants in so far as the differences between them do not affect the safety level and the other performance requirements of the product. Several family variants of the product may be marketed. These family variants are all based on the same design, but the (host-dependent) options, version, etc. differ. The product variants form, as it were, a product family only then when in all possible configurations and/or versions at least one part has certain uniqueness. Family name refers to the totality of all possible (family) variants.

#### Harmonised standard

A harmonised standard is a standard published by the European Commission in the Official Journal of the European Union under the scope of a Directive. Compliance to a harmonised standard provides presumption of compliance to the essential requirements of the Directive.

#### **Importer**

Any person who places on the market of the EEA, a product from a third country.

#### Internal control of production

A conformity assessment procedure whereby the manufacturer assesses the design and production of his products himself.

# ISO/IEC 17025

The standard for the accreditation of test laboratories in ISO/IEC 17025.

#### Kiwa

Notified Body under the LVD with identification number 0063.

Directive 98/13/EC, Annex 1.



#### Manufacturer

The person responsible for designing and manufacturing a product covered by a Directive with the view to placing it on the market of the EEA on his own behalf.

#### Nando

Nando is the website of the European Commission giving access to a database with all the designated and notified bodies under EU Directives.

### **Notified Body**

A Notified Body is a third party authorised to carry out the tasks relating to approvals described in a European Directive. In general, a Notified Body can be regarded as a competent approvals body in a field where approval (certification) of a product is compulsory by law. A Notified Body is designated by the Member State of its establishment. A Member State of the EEA (European Economic Area) can only designate bodies falling within its sphere of competence.

Bodies designated by a Member State should satisfy criteria relating to proficiency, independence, impartiality, etc. In this connection, European standards ISO/IEC 17065 and EN ISO/IEC 17021-1 are particularly important. The body is then notified to the European Commission and the other Member States of the EEA and thereby acquires the status of the "Notified body".

#### **OEM** products

An approval-holder may market the same product under different model designations and/or trademarks. One approval is issued for the product in which all the relevant model designations and/or trademarks are listed. (OEM = Original Equipment Manufacturer.)

#### Placing on the market

The first moment when a product, covered by a Directive, being made available, for payment or free or charge, on the market of the EEA with a view to its distribution and/or use in the territory of the EEA.

#### **Putting into service**

The first use by the end user within the EEA, of a product covered by a Directive.

#### Raad voor Accreditatie

The Accreditation Body in The Netherlands in called Raad voor Accreditatie (in Dutch) or Dutch Council for Accreditation (in English).

### Standard

A standard is a technical specification drawn up by a recognised standards organisation (CEN, CENELEC or ETSI) for repeated or continuous application, but with which compliance is not necessarily compulsory.

#### **Technical specification**

A technical specification is the specification contained in a document which lays down the characteristics required of a product such as quality levels, performance, safety, dimensions, including the requirements applicable to the product as regards terminology, symbols, tests and test methods, packaging, marking and labelling.

#### **Trademark**

Trademark refers to the generic (brand) name under which a certain product is marketed.

### **Model designation**

Model designation refers to the unique name under which a certain product is marketed.

#### **VROM**

The Dutch ministry responsible for the implementation of the LVD is called Ministry of Volkshuisvesting, Ruimtelijke Ordening en Milieu (VROM).



# Annex B The Declaration of Conformity

The Declaration of conformity is a document drawn up by the manufacturer, supplier or importer himself. The purpose of the declaration is to indicate that the product in question conforms to the standard(s) and Directive(s) to which the declaration refers. A model of the Declaration of Conformity is described in the standard EN45014, *General criteria for suppliers' declaration of conformity*.

All new-approach Directives require a Declaration of Conformity (to type) to be drawn up for each product. If multiple Directives apply you may also draw up one declaration for all these Directives together, in which you specify all the standards and references of all applicable Directives.

### B.1 Content of the declaration

The declaration must contain sufficient information to identify all the products referred to. At least the following information must be provided:

- the name and address of the manufacturer/importer issuing the declaration;
- the identification of the product (name, type or model, batch or serial number, possibly the origin and numbers of articles);
- an accurate, complete and clear statement of the standards and/or technical solutions referred to;
- the date of issue;
- name and signature or equivalent authentication of the authorised representative;
- the statement that the declaration has been issued entirely on the responsibility of the manufacturer/importer;
- a reference to the Directives that apply.



# B.2 Drawing up a declaration

It is recommended that declarations are drawn up on letter headed paper of the company and that original copies are forwarded to Kiwa together with the application in question. However, Kiwa can provide you with some generic declaration forms to complete.

Model 1: The Declaration of conformity to type relating to the LVD

Declaration of conformity		
We (Name and address)		
hereby declare entirely on our own responsibility that the product: (Name, type, etc.)		
to which this declaration relates, conforms to the following standard(s) or normative document(s): (Titles and publication dates of the standard(s))		
in accordance with the provisions of European Directive 2006/95/EC.		
(Place and date)		
(Name and signature)		



# Annex C Decisions under the LVD

Decisions of the European Commission related to the LVD (as per January 2007)

• None.



# Annex D Forms and documents

#### General

Several forms and documents are available to assist you in applying for product certification. The list below covers the most important documents relevant to the LVD.

For Attestation of Conformity:

(this document)

RF\_100 General Application form of Kiwa

**RQ\_160** Termination (expiration), reduction, suspension and withdrawal of Certificates

Kiwa can provide you with original copies of these documents, but you may also use photocopies or printouts obtained from the website.



# Annex E Additional information

For more information contact:

Kiwa Nederland B.V.

Phone: +31 88 998 3600 Fax: +31 316583189 Email: NL.ECP@Kiwa.com

Mailing Address: Wilmersdorf 50 7327 AC Apeldoorn The Netherlands

Web-site: <a href="http://www.Kiwa.com">http://www.Kiwa.com</a>