Conformity assessment procedures for the Tested by an Approved Laboratory (TAL) Scheme

RD_200, Issue 21

This guide describes the conformity assessment procedures and requirements for Radio Equipment, Telecommunication Terminal Equipment, Satellite Earth Stations and Marine Communication and Navigation Equipment. It is a prerequisite, that the products are tested by Kiwa, or by one of the Kiwa listed laboratories or by any accredited laboratory worldwide.

Revision record sheet

NOTE: The person who initiated the document or modified the document is responsible for maintaining this record sheet

Revision	Section number	Page number	Date	Remark(s)	issued by
15		2	07-04-2015	Insert Revision record sheet	WJJ
15	1.1		07-04-2015	Changed EN 45011 into ISO/IEC 17065	WJJ
15	2.3	6	07-04-2015	Removed Hermon and added IMQ	WJJ
15	2.3	6	09-04-2015	Removed Tajo Yuden	AG
16	2.3	6	27-05-2015	Name change of Labotech	AG
17	1.1	4	18-08-2016	Modified paragraph About Telefication	EB
	3.9	11	18-08-2016	Modified paragraph Termination (expiration), reduction, suspension and withdrawal of Certificates	EB
	2.3 Annex D	5, 21	18-08-2016	Changed Phone number	EB
	Front page	1	18-08-2016	Changed footer bank first page	EB
	Annex C	20	18-08-2016	Added RQ_160	EB
18	2.3	6	28-09-2016	IMQ removed from the list	AG
	7	16		Reference to accredited inspection body removed.	
19	7 & 8	16 & 18	23-01-2017	Reference “EN 45011, General criteria for suppliers declaration of conformity.” replaced by NEN-EN-ISO/IEC 17050-1/-2 incl. Annex B (template).	AG
				ISO/IEC Guide 2: 1991, replaced by ISO/IEC guide 2:2004 & reference to NEN-EN 45001 and ISO Guide 25 deleted (now ISO/IEC 17025). Global approach replaced by NLF.	
20	2.3	5	11-02-2022	Address updated.	AG
21	Complete document	All	25-05-2022	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 Manager
Revision : 21
Date : 25-05-2022

Verified by : Willem Jan Jong
Function : Manager Product Certification
Date : 25-05-2022

Released by : Axel Gase
Function : Quality Manager
Date of release : 25-05-2022

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1 Introduction

1.1 About Kiwa

Kiwa Nederland B.V. is a third party test laboratory and third party certification body. The Dutch Council for Accreditation (Raad voor Accreditatie: RvA) has accredited Kiwa to ISO/IEC 17025 (laboratory) and NEN-EN-ISO/IEC 17065 (product certification).

More information about Kiwa is available in *RD_560, About Kiwa.*

1.2 About this document

This document, conformity assessment procedure for the Tested by an Approved Laboratory (TAL), is intended as a guide for manufacturers and importers who want to have registered that one of their products is tested by Kiwa, or any accredited laboratory or a Kiwa-listed laboratory and is meeting the requirements.
The document describes the conformity assessment procedures that have to be followed to realise the registration. The conformity assessment procedures are derived from the “Kiwa Approach”.

2 Requirements

2.1 Overview

Equipment may obtain registration under this certification scheme if:

- The equipment is falling under the scope of this scheme;
- The equipment has been tested either by Kiwa, a Kiwa-listed laboratory or any Accredited laboratory worldwide, which is accredited to the test standards.
- The equipment is tested in accordance to one or more applicable standard(s);
- The equipment is compliant to the test standard(s).

2.2 Equipment under this scheme

The following equipment is falling under the scope of this scheme:

Radio Equipment, telecommunications terminal equipment and alarm components.

2.3 Accreditation and listing

A requirement of this certification scheme is that the test is performed under the accreditation or listing of the laboratory, which performed the test.

The laboratory of Kiwa is fulfilling this requirement.

Kiwa Nederland B.V.
Wilmersdorf 50
7327 AC Apeldoorn
The Netherlands
Phone: +31 88 998 3393

In conformance with the general quality policy of Kiwa accredited laboratories are accredited against ISO/IEC 17025. An accreditation body, which is member of the European co-operation for Accreditation (EA) or which has a Multilateral Agreement (MLA) with the EA, has done the accreditation.

Kiwa-listed laboratories are audited by the Certification department and are fulfilling the requirements as laid down in the document “RD_050, Requirements for Kiwa-listed laboratories”.

The laboratories, which are Kiwa-listed, are:

Labotech International Co., Ltd.

9-52 Ashihara-cho	(2-20 Nishinomiya Hama)
Nishinomiya-shi	(Nishinomiya-shi)
Hyogo 662-8580	(Hyogo 662-0934)
Japan	

2.4 Standards

The relevant standards are listed in document RE_200.
This document can be found at https://www.kiwa.com/

2.5 Compliance

A requirement of this certification scheme is that the product is compliant to the applicable standards.

3 Conformity assessment procedures

The applicable conformity assessment procedures are derived from the “Kiwa Approach”.

The conformity assessment procedures of this certification scheme are Type-examination (module B) followed by Conformity to Type (module C).

Each of these procedures imposes a number of rules and obligations on the applicant. The procedures are described in detail in the following sections.

3.1 Flow diagram

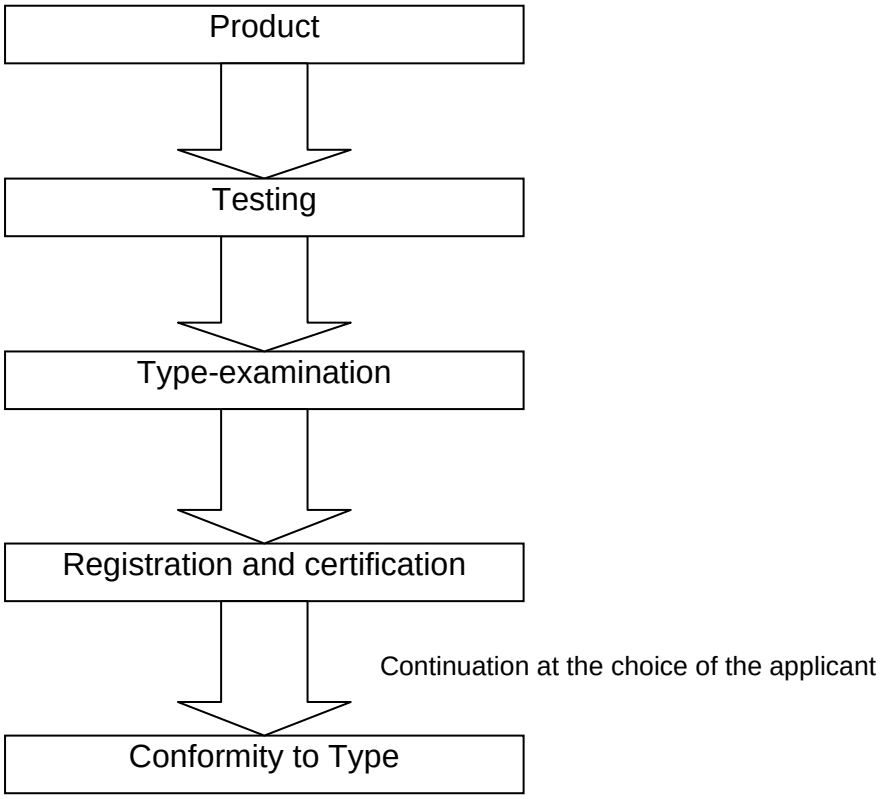

Figure 1: The assessment procedures

In the Type-examination procedure, Kiwa assesses whether the product conforms to the requirements. The assessment is generally based on test reports.

The technical documentation, to be submitted with the Type-examination application, should provide information about the design, the production process and the operation of the product.

3.2 The application

The type-examination can take the following forms:

1. The applicant has the product tested by Kiwa or by a Kiwa-listed laboratory or accredited laboratory of his choice. He should then submit the application together with the test reports and all other relevant documentation to Kiwa;
2. The applicant submits an application directly to Kiwa together with the relevant supporting documentation. Kiwa will assess the submission and additionally necessary tests of the product will be consulted with the applicant.

There are no restrictions concerning who may apply or concerning the place of establishment of the applicant; everyone may submit an application. However, the manufacturer should preferably submit the application

Application forms are available from Kiwa (see also Annex C). The application and the accompanying documentation may be submitted in Dutch or English.

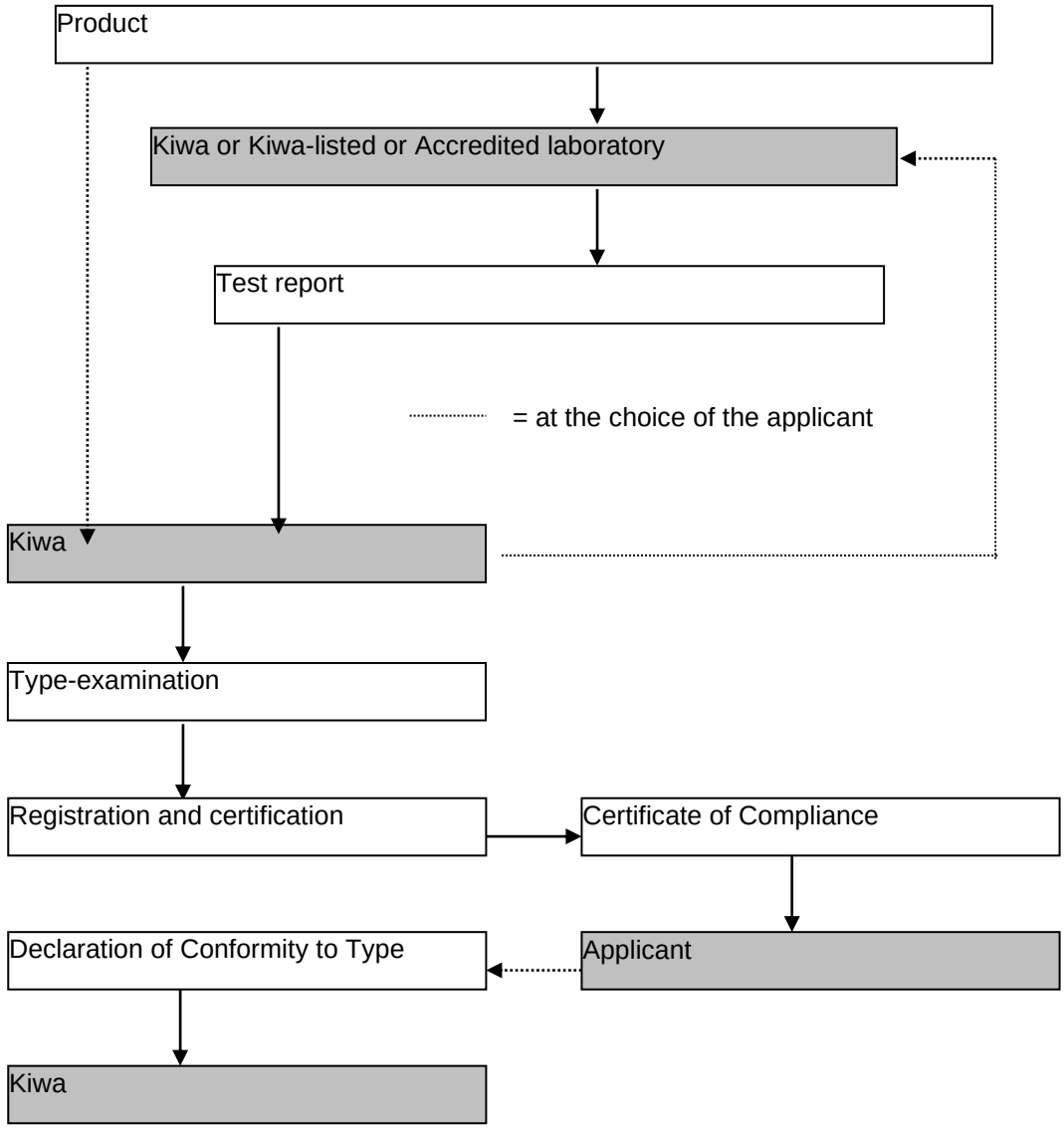

Figure 2: The Type-examination and Conformity to Type procedures.

3.3 Required documentation

The (technical) documentation to be submitted with the application must contain the information necessary to assess the product, such as:

a) An explanation providing a brief overview of the documentation;
b) A general type-description so that the product can be identified (preferably one or more clear photographs);
c) Design and manufacturing drawings, lists of components, subassemblies, circuits, etc.;
d) Test reports, and details of the standard(s) used;
e) A user manual (or a draft);

Certification will use the documentation and test results to ascertain whether the product satisfies the requirements of Kiwa.

3.4 Product variants

Product
A product is equipment that is unique in its construction.
A product may be marketed as a variant, however all of these variations need to be assessed by Kiwa. OEM products and product variants can be added to the register and to the Certificate of Compliance if they comply with the following conditions.

OEM product
One may market the same product under different type designations and/or trademarks. The products are 100% identical, in construction, hardware, software and physical outlining
(OEM = Original Equipment Manufacturer).

Product variants category one
These are products that are almost identical, but differ in some small detail. Products that fall under this category are for instance the so-called stripped versions, where components are skipped to achieve for example less extensions etc.

Product variants category two
Products that are identical at large, but differ more than the previous mentioned products, will fall under category two. Examples of this product are a different PCB layout is used while the electronic design is the same, addition of more options to the same basic product, etc.

3.5 The Declaration of Conformity to Type

Where the use of the Mark is desired, the applicant must draw up a *Declaration of Conformity to Type* for the type of product tested. This is a document in which the applicant declares that the products to be produced will be equal to the product assessed in the Certificate of Compliance.
If the applicant will not use the Mark it is not obligatory to draw up a *Declaration of Conformity to Type*.

A model of the *Declaration of Conformity to Type* is given in Annex B.

3.6 The Certificate of Compliance

Products may not be marked before a Certificate of Compliance has been issued. Kiwa will, if the Type-examination + Conformity to Type procedures have been completed successfully, register the

product and issue a Certificate of Compliance. Any Certificate of Compliance issued by Kiwa will contain at least the following data:

- The name and address of the manufacturer and the applicant, and data to identify the product;
- The name and address of the Certificate-holder;
- A reference to this certification scheme;
- The registration/certificate number;
- A description of the product;
- The type designation of the product and of each variant if any;
- Date of issue and signature.

The annexes accompanying the Certificate of Compliance contain information on the technical specifications on the basis of which the Certificate of Compliance was issued and any conditions for its validity, such as:

- A description of product use;
- References to the technical standard(s) to which the product is assessed and complies with;
- The software version affecting the compliance of the product where applicable.

The Certificate of Compliance is not transferable without the intervention of Kiwa. See also *'Modifications to Certified Product'.*

3.7 Addition to the Certificate of Compliance

The Certificate of Compliance is valid only for products, which are identical with the tested sample(s). Products however are often modified after they have been certified. Any changes, that could affect the performance characteristics covered by the conformity assessment requirements, should be discussed with Kiwa. Depending on the modifications, Kiwa may require additional tests to be carried out, sometimes an additional inspection by Kiwa will suffice. See also *'Modifications to Certified Product'*.

Where necessary, Kiwa will issue an amendment to the Certificate of Compliance.

3.8 Record of complaints

The certificate holder shall keep a record of all complaints and remedial actions relative to the products covered by any certificate granted by Kiwa.

3.9 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 Modifications to Certified Product

4.1 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 type designation and/or trademark.

Modifications of a technical nature:
- Addition of new product variants;
- Modification of product hardware/software;
- Modifications not affecting the technical requirements.

4.2 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 administrative changes.

Comments
This modification does not affect the Type examination. Kiwa will record the new details and send the applicant a confirmation, which should be kept with the Certificate of Compliance. Certificates already issued remain valid.

4.3 Change of certificate-holder

The Certificate of Compliance is drawn up in the name of the certificate-holder and is not transferable without the intervention of Kiwa. The name of the certification-holder can, however, be changed, in which case the new certification-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.[1] All the type 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(s) 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 certificate. The new certificate-holder draws up a Declaration of Conformity for each type and sends a copy to Kiwa.

If the new certificate-holder demonstrates that he meets all the relevant requirements, Kiwa will issue an *Addition to the certificate*, in which the details of the new certificate-holder are stated.

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1 If the holder has been declared bankrupt, the product is the certificate-holder.

4.4 Alteration/addition of a type designation and/or trademark

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

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

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

An *Addition to the certificate* will be issued to the certificate-holder. All the relevant type designations and/or trademarks are listed in an annex to the Certificate of Compliance.

4.5 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 type 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 Kiwa or Listed laboratory or Accredited Laboratory.

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

4.6 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 technical requirements.

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

The manufacturer or importer draws up a new *Declaration of conformity (to type)* and sends a copy to Kiwa. Kiwa issues an *Addition to the Certificate of Compliance*.

4.7 Modifications not affecting the requirements

Modifications to products, which do not and cannot affect conformity with the 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.

5 The public available information

Application to this certification scheme entitles Kiwa to make the following information available to any third party via the World Wide Web or any other means:

- Name of certificate-holder;
- Certification/registration number;
- Name of manufacturer;
- Name of trademark;
- Name(s) of product type (type designation);
- List of standards tested.

6 Reproduction of the Certificate of Compliance

The certificate-holder is entitled to make reproductions of the Certificate of Compliance. It is recommended to add a copy of the Certificate of Compliance to the documentation supplied with products.

7 Annex A Abbreviations and paraphrases

Accreditation
Accreditation means assessed by a member of the European co-operation for Accreditation (EA) or by an organisation with a Multilateral Agreement signed with the EA. An accredited laboratory is fulfilling the requirements of ISO/IEC 17025.

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 by this certification scheme.

Certificate-holder
The certificate-holder is the person to whom a certificate is granted.

Conformity to Type procedure
A certification procedure whereby the manufacturer is declaring that the products produced are equal to the one tested in respect of the requirements relevant for the applicable certification scheme.

Certification
A procedure whereby a third party gives written assurance that a product, process or service conforms to specified requirements (ISO/IEC Guide 2: 2004).

Conformity assessment
Systematic examination of the extent to which a product, process or service satisfies further specified requirements (ISO/IEC Guide 2: 2004).

Declaration of Conformity to Type
The *Declaration of Conformity to Type* is a document drawn up by the Manufacturer, Supplier or Importer. It should indicate that the product concerned is equal to the product tested and certified with respect to the requirements of this certification scheme. A model of the *Declaration of Conformity to Type* is described in standard NEN-EN-ISO/IEC 17050-1, *General criteria for suppliers' declaration of conformity*.

Family
A type may comprise several product variants in so far as the differences between them do not affect the 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 options, version, etc. differ. Family name refers to the totality of all possible (family) variants.

Manufacturer
The manufacturer is the person responsible for designing and manufacturing a product.

Notified Body
A Notified Body is a certification body designated by a Member State of the European Union to grant approvals under the directive(s), mentioned in their designation. Member States have to notify their designations to the European Commission.

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

Standard
A standard is a technical specification drawn up by a recognised standards organisation (CEN, CENELEC or ETSI) or by Kiwa 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.

Kiwa-listed laboratory
Kiwa-listed laboratories are audited by Certification and are fulfilling the requirements as laid down in the document "RD_050, Requirements for Kiwa-listed laboratories".

Kiwa
Kiwa is an accredited certification body, an accredited test laboratory.

Kiwa Approach
A general structure for product certification developed by Kiwa. The Kiwa Approach is a superset of the New legislative Frame Work regulation EC 765/2008 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, which are intended to be used in the technical harmonisation directives).

Trademark
Trademark refers to the generic (brand) name under which an apparatus is marketed.

Type designation
Type designation refers to the unique name under which an apparatus is marketed.

Type-examination procedure
A certification procedure whereby the design, possibly by means of tests, of a representative specimen of the production envisaged is assessed.

8 Annex B Declaration of Conformity to Type

The *Declaration of Conformity to Type* 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 is equal with the product tested and certified with respect to the requirements of this certification scheme. A model of the *Declaration of Conformity to Type* is described in the standard NEN-EN-ISO/IEC 17050-1, *General criteria for suppliers' declaration of conformity*.

8.1 Content of the declaration

The declaration must contain sufficient information to identify all the products referred to.
As a minimum the following information shall 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 legislation that applies.

8.2 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

Supplier's declaration of conformity (in accordance with ISO/IEC 17050-1)

1) **No.** .....

2) **Issuer's name:** .....

Issuer's address: .....

.....

3) **Object of the declaration:** .....

.....

.....

4) **The object of the declaration described above is in conformity with the requirements of the following documents:**

	Documents No.	Title	Edition/Date of issue
5)	.....	.....	.....
	.....	.....	.....
	.....	.....	.....

Additional information:

6) .....

.....

.....

Signed for and on behalf of:

.....

.....

(Place and date of issue)

7) ....

(Name, function) (Signature or equivalent authorized by the issuer)

9 Annex C 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 for this certification scheme.

RD_200 Conformity assessment procedures for the TAL Scheme (this document)

RF_100 General application form

RF_258 Declaration of Conformity to Type (TAL Scheme)

RQ_160 Termination (expiration), reduction, suspension and withdrawal of Certificates

Kiwa can provide you with original copies of these forms, but you may also use photocopies or printouts obtained from the web site. https://www.kiwa.com/

10 Annex D Additional information

For more information contact:

Kiwa Nederland B.V.

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

Mailing Address:
Wilmersdorf 50
7327 AC Apeldoorn
The Netherlands

Web-site: http://www.Kiwa.com