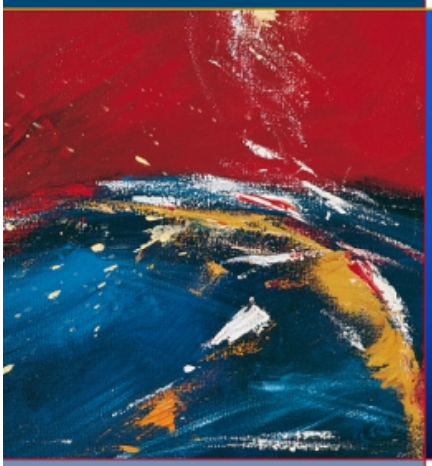
Protocol K15010
December 2016

Kiwa Protocol

for products in contact with drinking water



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Validation
This Protocol has been validated by the responsible Division Director of Kiwa in December 2016

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1 Introduction

1.1 General

For the performance of its certification work, Kiwa is bound to the requirements as included in the clause 4.6 “conditions and procedures for granting, maintaining, extending, suspending and withdrawing certification” of NEN-EN-ISO/IEC 17065.

1.2 Field of application / scope

Protocol K15010 describes the hygienic requirements for products, components, or materials that come into contact with drinking water.

Remark:

Protocol K15010 is intended for products already described with an existing guideline (BRL) and for products according to Manual K15013.

For all requirements – excluding the requirements in clause 4.2 – see the relevant guideline (BRL) or Covenant (according to Kiwa Manual K15013).

1.3 Acceptance of test reports provided by the supplier

If the supplier provides reports from test institutions or laboratories to prove that the products meet the requirements of the Covenant, the supplier shall prove that these reports have been drawn up by an institution that complies with the applicable accreditation standards, namely:

- NEN-EN-ISO/IEC 17020 for inspection bodies;
- NEN-EN-ISO/IEC 17021 for certification bodies certifying systems;
- NEN-EN-ISO/IEC 17024 for certification bodies certifying persons;
- NEN-EN-ISO/IEC 17025 for laboratories;
- NEN-EN-ISO/IEC 17065 for certification bodies certifying products.

1.4 Quality declaration

The declaration to be issued by Kiwa based on Protocol K15010 (concerning the Hygienic aspects) is an inseparable part of an quality declaration according to:

1:a Kiwa Guideline (BRL) ;

or

2: Kiwa Manual K15013 (Covenant, see definitions).

2 Terms and definitions

2.1 Supplier:
the party that is responsible for ensuring that the products meet and continue to meet the requirements on which the certification is based.

2.2 IQC scheme (IQCS) :
a description of the quality inspections carried out by the supplier as part of his quality system.

2.3 Board of Experts:
the Board of Experts “Water Cycle” (CWK).

2.4 Evaluation Guideline (BRL)
the agreements made within the Board of Experts on the subject of certification.

2.5 Product:
products, components or materials that come into contact with drinking water, as defined and covered by the Kiwa watermark.

2.6 Product requirements:
requirements made specific by means of measures or figures, focusing on (identifiable) characteristics of products and containing a limiting value to be achieved, which limiting value can be calculated or measured in an unequivocal manner.

2.7 Pre-certification tests:
tests in order to ascertain that all the requirements recorded in the Protocol are met.

2.8 Inspection tests:
tests carried out after the certificate has been granted in order to ascertain whether the certified products continue to meet the requirements recorded in the Protocol.

2.9 Drinking water:
water intended or partly intended for drinking, cooking or food preparation or other domestic purposes, but does not include hot water, and is made available by pipeline to consumers or other customers.

2.10 Hot tap water:
water intended or partly intended for drinking, cooking or food preparation or other domestic purposes, which is heated before it is made available for those applications.

2.11 Product certificate:
a document, in which Kiwa declares that a product may, on delivery, be deemed to comply with the product specification recorded in the product certificate.

2.12 Testing:
for this Protocol “testing” is the following:
All necessary testing to ensure that the product shall meet the requirements as stated with this Protocol.

2.13 Covenant:
A Covenant is a statement of endorsement, which means an explicit statement of approval, always in relation to the content of that specific Covenant according to Kiwa Manual K15013.

3 Procedure for granting the quality declarations

3.1 Pre-certification tests

The pre-certification tests to be performed are based on the (product) requirements as included in this Protocol including the test methods and contain,
depending on the nature of the product to be certified:

- type testing to determine whether the products comply with the product and/or functional requirements,
- production Process Assessment,
- assessment of the quality system and the IQC-scheme,
- assessment on the presence and functioning of the remaining procedure.

3.2 Granting the quality declarations

After finishing the pre-certification tests the results are presented to the person deciding on granting of the certificate. This person evaluates the results and decides whether the certificate can be granted or additional data and/or tests are necessary.

4 Product Requirements

4.1 General

This chapter contains the requirements for products in contact with drinking water, have to be fulfilled.

4.2 Requirements to avoid deterioration of the quality of drinking water

The requirements in this chapter are public law requirements.

To prevent harmful effects on the quality of drinking water, the following government imposed provisions apply.
Products and materials which (may) come into contact with drinking water or warm tap water, shall not release substances in quantities which can be harmful to the health of the consumer, or negatively affect the quality of the drinking water. Therefore, the products or materials shall meet toxicological, microbiological and organoleptic requirements as laid down in the currently applicable " Materials and chemicals in the supply of drinking water and warm tap water Regulation ", (published in the Government Gazette). Consequently, the procedure for obtaining a recognised quality declaration, as specified in the currently effective Regulation, has to be concluded with positive results.
Remark: with a positive result - concerning the aspects under point 4.2 and all requirements according to the relevant guideline (BRL) or Covenant. - a certificate is granted.

4.3 Installation instructions

The supplier shall provide installation instructions where applicable. A reference to these instructions shall be made at or near to the packaging. The instructions must contain specific information with regard to storage, safety, transport, the use of the product, processing temperature, and specific installation guidelines.

4.4 Protection of products during transport and storage

When applicable, the products shall be protected during storage and transport to prevent contamination of all parts intended to come in contact with drinking water.
See for information Annex II: “Guidance for prevention of contamination during transport and storage”.

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5 Marking

5.1 General

The products shall be marked with following indelible marks and indications:

- name or logo of the manufacturer;
- data or code indicating the date of production;
- type indication

5.2 Certification mark

After concluding a Kiwa certification agreement, the certified products shall, beside the marks indicated in the respective standards, be indelible marked with the Kiwa Water Mark:

KIWA

or the simplified version of the Water Mark :

KIWA 

6 Requirements in respect of the quality system

This chapter contains the requirements which have to be met by the supplier's quality system.

6.1 Manager of the quality system

Within the supplier's organizational structure, an employee who will be in charge of managing the supplier's quality system must have been appointed.

6.2 Internal quality control/quality plan

The supplier shall have an internal quality control scheme (IQC scheme) which is applied by him.

The following must be demonstrably recorded in this IQC scheme:

- which aspects are checked by the producer;
- according to what methods such inspections are carried out;
- how often these inspections are carried out;
- in what way the inspection results are recorded and kept.

This IQC scheme should at least be an equivalent derivative of the model IQC scheme as shown in Annex I.

6.3 Procedures and working instructions

The supplier shall be able to submit the following:

- procedures for:
  - dealing with products showing deviations;
  - corrective actions to be taken if non-conformities are found;
  - dealing with complaints about products and/or services delivered;
- the working instructions and inspection forms used.

6.4 Other requirements

The supplier must be able to submit the following:

- the organisation's organogram;
- qualification requirements of the personnel concerned.

7 Summary of tests and inspections

This chapter contains a summary of the following tests and inspections to be carried out in the event of certification:

- pre-certification tests;
- inspection test as to toxicological requirements and product requirements;
- inspection of the quality system.

7.1 Test matrix

In table 1 the test matrix is given.

Table 1 – Test matrix.

Description of requirement	**Article no. of Protocol Clause**	**Tests within the scope of:**	
		Pre-certification	**Supervision by Kiwa after granting of certificate** [a,b)]
Requirements to avoid deterioration of the quality of the drinking water	4.2	X	X
Installation instructions	4.3	X	X
Protection during transport and storage	4.4	X	X
Marking	5	X	X

a) In case the product or production process changes significantly, it must be determined whether the performance requirements are still met.

b) All product characteristics that can be determined within the visiting time (maximum 1 day) are determined by the inspector or by the supplier in the presence of the inspector. In case this is not possible, an agreement will be made between the certification body and the supplier about how the inspection will take place. The frequency of inspection visits is defined in chapter 8.6 of this evaluation guideline.

7.2 Inspection of the quality system

The quality system will be checked by Kiwa on the basis of the IQC scheme.
The inspection contains at least those aspects mentioned in the Kiwa Regulations for Product Certification.

8 Agreements on the implementation of certification

8.1 General

Beside the requirements included in this Protocol, the general rules for certification as included in the Kiwa Regulations for Product Certification also apply.

These rules are in particular:

- the general rules for conducting the pre-certification tests, in particular:
  - the way suppliers are to be informed about how an application is being handled;
  - how the test are conducted;
  - the decision to be taken as a result of the pre-certification tests.
- the general rules for conducting inspections and the aspects to be audited,
- the measures to be taken by Kiwa in case of Non-Conformities,
- the measures taken by Kiwa in case of improper use of Certificates, Certification Marks, Pictograms and Logos,
- terms for termination of the certificate,
- the possibility to lodge an appeal against decisions of measures taken by Kiwa.

8.2 Certification staff

The staff involved in the certification may be sub-divided into:

- Certification assessor (**CAS**): in charge of carrying out the pre-certification tests and assessing the inspectors' reports;
- Site assessor (**SAS**): in charge of carrying out external inspections at the supplier's works;
- Decision maker (**DM**): in charge of taking decisions in connection with the pre-certification tests carried out, continuing the certification in connection with the inspections carried out and taking decisions on the need to take corrective actions.

8.2.1 Qualification requirements

The following qualification requirements have been for the subject matter of this evaluation guideline (see Table 2):

Table 2 – Qualification requirements of certification staff.

Basis requirements	Evaluation criteria
Knowledge of company processes Requirements for conducting professional audits on products, processes, services, installations, design and management systems.	*Relevant experience: in the field* **SAS, CAS** : 1 year **DM**: 5 years inclusive 1 year with respect to certification Relevant technical knowledge and experience on the level of: **SAS**: High school (MBO) **CAS, DM** : Bachelor (HBO)
Competence for execution of site assessments. Adequate communication skills (e.g. reports, presentation skills and interviewing technique).	**SAS**: Kiwa Audit training or similar and 4 site assessments including 1 autonomic under review.
Execution of initial examination	**CAS**: 3 initial audits under review.
Conducting review	**CAS**: conducting 3 reviews

	Certification assessor	Site assessor	Decision maker
Education - specific	• Protocol-relevant technical education • specific studies and training (know-how and skills)	• Protocol -relevant technical education • specific studies and training (know-how and skills)	• not applicable.
Experience - specific	• Detailed knowledge of the Protocol and 4 certification tests carried out on the basis of the Protocol or similar	• Detailed knowledge of the Protocol and 4 inspections carried out on the basis of the Protocol or one similar.	• general knowledge of the Protocol

The level of education and experience of the certification staff involved should be demonstrably recorded.

8.2.2 Qualification

The qualification of the Certification staff shall be demonstrated by means of assessing the education and experience to the above mentioned requirements. In case staff is to be qualified on the basis of deflecting criteria, written records shall be kept.

The authority to qualify staff rests with the:

- Decision maker: qualification of Certification and Site assessors;
- Management of the certification body: qualification of Decision makers.

8.3 Report Pre-certification tests

Kiwa records the results of the pre-certification tests in a report.
This report shall comply with the following requirements:

- completeness: the report provides a verdict about all requirements included in the evaluation guideline;
- traceability: the findings on which the verdicts have been based shall be recorded and traceable;
- basis for decision: the Decision maker shall be able to base his decision on the findings included in the report.

8.4 Decision for granting the certificate

The decision for granting the certificate shall be made by a qualified Decision maker which has not been involved in the pre-certification tests. The decision shall be recorded in a traceable manner.

8.5 Layout of quality declaration

The product certificate shall be in accordance with the model included in Annex I.

8.6 Nature and frequency of third party audits

The certification body shall carry out audits on site at the supplier at regular intervals to check whether the supplier complies with his obligations. At the time this Protocol entered into force, the frequency of audits amounts at least one audit on site per year for suppliers with a quality management system (in accordance with ISO 9001) for their production, which has been certified by an acknowledged body (in accordance with ISO/IEC 17021) and where the IQC scheme forms an integral part of the quality management system.
In case the production of the supplier is not certified against ISO 9001, the frequency of the audits on site may be increased to at least two per year.

The audit program on site shall cover at least:

- the suppliers IQC scheme and the results obtained from inspections carried out by the supplier;
- the correct way of marking certified products;
- compliance with required procedures.

The results of each audit shall be recorded in a traceable manner in a report.

8.7 Non conformities

When the certification requirements are not met, measures are taken by Kiwa in accordance with the sanctions policy, namely:

what is published on the Kiwa service portal (www.kiwa.nl).

9 Titles of standards

9.1 Public law rules

In Table 3, the public rules that have to be fulfilled are listed.

Table 3 – Public law rules (*in force for The Netherlands*).

Standard	Title
"Staatscourant" (Government Gazette) from 18 July 2011, no. 11911	"Regeling Materialen en Chemicaliën drink- en warm tapwatervoorziening" (Materials and chemicals in the supply of drinking water and warm tap water Regulation)

9.2 Standards / normative documents

The relevant normative documents (standards) for this evaluation guideline are listed in the Table 4.

Table 4 –Relevant normative documents/standards

Standard *	Title
EN-ISO 9001	Quality management systems - Requirements
NEN-EN ISO/IEC 17020	Conformity assessment - General criteria for the operation of various types of bodies performing inspection
NEN-EN ISO/IEC 17021	Conformity assessment - Requirements for bodies providing audit and certification of management systems
NEN-EN ISO/IEC 17024	Conformity assessment - General requirements for bodies operating certification of persons
NEN-EN ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories
NEN-EN ISO/IEC 17065	Conformity assessment - Requirements for bodies certifying products, processes and services
Kiwa Manual K15013	Kiwa Covenants for products and processes

I Annex: Model IQCS scheme

Model IQCS scheme

Inspection subjects	**Inspection aspects**	**Inspection method**	**Inspection frequency**	**Inspection registration**
Raw materials or materials supplied: - recipe sheets - incoming goods inspection raw materials				
Production process, production equipment, plant: - procedures - working instructions - equipment - release of product				
Finished-products				
Measuring and testing equipment - measuring equipment - calibration				
Logistics - internal transport - storage - Preservation - packaging - identification				

II Annex: Guidance for prevention of contamination during transport and storage

a) Importance of a hygienic operation

The impact of pollution can have big consequences for the water distribution [1)] and need substantial efforts to clean the system.

b) Protection of the used products

The primary task in this case is “prevention” and secondary is also important the preparation of the main for the actual drinking water transport.

For all products coming from the production location, until installation in the drinking water system the same “preventive” measurements shall be taken [2)], to prevent pollution.
Therefore manufacturers shall have a procedure how to prevent pollution of certified (drinking water) products during production, transport and storage.

c) Requirements for the protection of products

For all preventive (protective) actions taken to protect the products against pollution it is important that the protection will last for the complete process of storage, transport and again storage.

remark :
1) mostly this is a microbiological contamination coming from the surrounding area on macro- and micro scale (like dust, but also feces and dead beasts.
2) “protection” is the combination of packaging and closing the pipe/fitting ends.