Certification scheme

Products and components in contact with water intended for human consumption (drinking water) on the basis of the indications of Ministerial Decree nr. 174/2004

06	15/03/2022	Revisione ed aggiornamento, eliminazione dei riferimenti alle categorie di prodotto A e B, eliminazione All. 2	OPE	GEA DIR GOV	DIR OPE
05	12.03.2021	Modifica titolo a seguito autorizzazione Accredia e aggiornamento riferimenti normativi	OPE	DIR ISG	DIR OPE
04	18.12.2020	Integrazioni ai paragrafi Prove Iniziali e Prove di Sorveglianza a seguito richieste Accredia	OPE	ISG	DIR OPE
03	27/05/2019	Revisione modalità campionamento e documenti commerciali di riferimento	OPE	ISG	DIR OPE
02	12/02/2018	Revision of the material sheets	OPE	ISG	DIR OPE
01	30/10/2017	Revision after ACCREDIA document verification. Addition of Ann. 3 and 4.	OPE	ISG	DIR OPE
00	15/09/2016	Issue	PR&EN	ISG	DIR
Rev.	***Date***	***Description***	***Drawn up***	***Verified***	***Approved***
IDENTIFICATION: 0415CS_06_EN					

PRODUCT/SERVICE DESCRIPTION

DEFINITION
The certification scheme defines the methods and conditions that an Organisation must comply with to obtain and maintain Certification or Approval of "Product compatible with water intended for human consumption" issued by ICIM and to be registered in the Registry of Businesses/Product in possession of Certification (Registry). *The scheme is developed to certify products and components that come into contact with water intended for human consumption according to the requirements defined in Annex 1 of this certification scheme. These requirements have been developed with reference to national, European and international laws and regulations.* *No substances or materials for the manufacture of products and components, or impurities associated with these substances or materials, must remain in water intended for human consumption in concentrations higher than necessary for the purpose of their use and these substances, materials or impurities do not, either directly or indirectly, reduce the protection of human health.* ***Manufacturing and Control Plan (MCP):*** *Operational planning tool of the Organisation which sets forth in detail the sequences of the manufacturing activities and/or processes and the control methods which affect product quality with reference to the relative regulatory documents.* ***Series/Family:*** *Group of products which have homogeneous technical and construction features.* ***Product:*** *item in contact with water for human consumption made with suitable material/s upon contact with water for human consumption, which must comply with the requirements defined in Annex 1 of this scheme.* ***Certification:*** *issued by a third party for the conformity of products/processes/systems or individuals (ISO/IEC 17000:2004). This procedure demonstrates through evaluations, tests and inspections if the specific requirements related to a product have been respected, also through periodic monitoring (annual monitoring visits) it evaluates the maintenance of these requirements.* ***Approval:*** *issued by a third party for the conformity of products/processes/systems or individuals (ISO/IEC 17000:2004). This procedure demonstrates through documental assessment of the chemical formulation of the product and the tests (performed by the Organisation) if the specific requirements related to a product have been respected, also through periodic monitoring (monitoring visits with varying frequency) it evaluates the maintenance of these requirements.*

REFERENCE STANDARDS
Standards and Regulations valid at the date of this document ***REGULATIONS*** ***ICIM 0001CR*** *ICIM General Regulation* ***ICIM 0003CR*** *Regulation for the certification of products and services* ***ICIM 0260CR*** *User manual of the ICIM S.p.A. Certification Marking* ***LAWS*** ***Ministry of Health Decree*** *no. 174 of 6 April 2004 "Regulations concerning the materials and articles that can be used in fixed systems of collection, treatment, delivery and distribution of water intended for human consumption"* ***Ministry of Health Decree*** *of 21 March 1973 "Hygiene regulation of packaging, containers, equipment intended to come into contact with foodstuffs or with substances for personal use" as amended."* ***Decree of the President of the Republic*** *no. 777 of 23 August 1982* "Implementation of Directive (EEC) no. *76/893 on materials and articles intended to come into contact with foodstuffs"* ***Decree of the Ministry of Health*** *of 4 April 1985 "Regulation of ceramic articles intended to come into contact with foodstuffs"* ***(It.) Legislative Decree*** *no. 108 of 25 January 1992 "Implementation of Directive no. 89/109/EEC concerning materials and articles intended to come into contact with foodstuffs"* ***Decree of the Ministry of Health*** *of 18 April 2007 no. 76 "Regulation on the hygiene control of materials and articles of aluminium and aluminium alloys intended to come into contact with food".* ***Reg. EU no. 10/2011*** *concerning plastic materials and articles intended to come into contact with foodstuffs"* *Council* ***DIRECTIVE 98/83/EC*** *of 3 November 1998 concerning the quality of water intended for human consumption* ***Legislative Decree*** *of 2 February 2001, no. 31 "Implementation of Directive 98/83/EC on the quality of water intended for human consumption"* ***OTHER*** *German Federal Environmental Agency (UBA) "Acceptance of metallic material used for products in contact with drinking water Part B – 4MS with Common Composition Lists"* ***STANDARDS*** *The applicable standards are indicated in the sheets referred to in Annex 1*
DESCRIPTION
To certify products intended to be in contact with water intended for human consumption, as well as their components (elbows, shut-off valves, gaskets, etc.), compatibly with the characteristics of water intended for human consumption. Furthermore, they must not under normal or foreseeable conditions of use and installation, alter the water placed in contact with them: *1) making it harmful to human health;* *2) and unfavourably changing its organoleptic, physical, chemical and microbiological characteristics.*

IDENTIFICATION CHARACTERISTICS
The basic characteristics that identify the series/family of homogeneous products (models) are the following: *a) GEOMETRY: Products belonging to the same series/family must have the same geometry (shape) and proportionally the same wet surface (permissible variation rate ≤ ± 5%)* *b) TYPE: The products belonging to the same series/family must be of the same type, i.e. perform the function for which they are designed in the same way (for e.g. press fittings, threading, welding)* *c) MATERIALS: The products belonging to the same series/family must have homogeneity of materials and treatments used for the components.*
*The characteristics that are allowed in the **variants**, provided they are declared in the construction drawings and in the bill of materials, are the following:* *a) GEOMETRY: Additional components related to product dimensions (for e.g. number of impellers in multistage pumps), or specular shapes (for e.g. male/female thread terminal), etc.* *b) MATERIALS: Alternative surface treatments or materials used for customisation as long as they are provided with suitable documentation supplied by the manufacturer (e.g. seals, painting)*

GENERAL CONDITIONS OF CERTIFICATION

CERTIFICATION TYPE
VOLUNTARY *Involves affixing the ICIM mark as per the document ICIM 0260CR.*
TYPE OF INTERVENTION
ICIM operates according to regulation ICIM 0003CR, there are no additional interventions to those indicated by the reference standards and laws.
Other
NOTES

APPLICATION FOR CERTIFICATION

ADDITIONAL DOCUMENTATION
The additional documentation in relation to what is required by ICIM regulation 0003CR, is the following: ▪ *Document illustrating the production of the Organisation (catalogues, advertising material, etc.);* ▪ *copy of the Quality System Certification in compliance with the UNI EN ISO 9001 standards* ▪ *technical documentation of the product subject to the Application (see following paragraph)* *The Application, where required, shall be accompanied by specification of the place where the product subject to certification can be examined and taken.* *This documentation should not include detailed plans of the construction details and other detailed information, concerning the sub-assemblies used for the manufacture of the product, unless the Organisation deems that knowledge of them is necessary for verification of conformity with the reference standards and regulations.*
TECHNICAL DOCUMENTATION
The technical documentation of the product subject to the Application must be drafted in Italian (if the Organisation is not Italian, then English or another language accepted beforehand by ICIM can be used) and sent to ICIM, for each type, for each variant and for each Production Unit, possibly on electronic support (CD rom or non rewritable DVDs) or sent by email. *It provides details on the characteristics and technical requirements of the products, according to the normative reference document; in particular, it also provides details on the characteristics of compatibility with drinking water for human consumption.* *Any subsequent changes to what is indicated in the technical documentation must be documented and communicated to ICIM before actually proceeding to the execution phase, in accordance with the provisions of this certification scheme and regulation ICIM 0003CR.* *The technical documentation must have an index and include at least:* ▪ *Manufacturing and Control Plan, with any support procedures, and the product traceability system,* ▪ *facsimile of the marking (on product, packaging and accompanying documents),* ▪ *reproduction of the registered trademark and/or product mark (if any),* ▪ *elements to identify the series/family of products subject to certification (identification of models and construction variants),* ▪ *product bill of materials,* ▪ *assembly drawings with an explanatory section on product operation and reference to the materials of the components in direct contact with water;* ▪ *list of materials of components of the product classified according to European standards;* ▪ *verifiable or documentable chemical-physical characteristics of the materials used* ▪ *for components made of plastic: declaration of conformity to Reg. EU no. 10/2011 of the raw material and of the materials used as auxiliaries (e.g. additives)* ▪ *for components in elastomeric material: declaration by the manufacturer with the reference compound and declaration that the material contains substances permitted by national or international legislation (eg FDA) relating to materials intended to come into contact with drinking water, with the conditions, limitations and tolerances of use provided therein.* ▪ *for components in metallic material data relating to the composition of the metallic material* ▪ *any heat treatment (where applicable),* ▪ *any surface treatments (e.g. galvanising, painting, etc.),* ▪ *installation, use and maintenance instructions,* ▪ *information on:*   ▪ *Name of the Production Unit, if different from the Organisation requesting product certification*   ▪ *Place or places of manufacture,*   ▪ *Relations between the applying organisation and the manufacturer (for example contracts),*   ▪ *copy of the agreements with main suppliers (where applicable)*
NOTES

CERTIFICATION

APPLICATION EXAMINATION
METHOD TO BE APPLIED
ICIM evaluates the completeness and the contents of the documentation of the Application and of the annexes as per ICIM regulation 0003CR. *From the detailed analysis of the data provided by the Organisation, ICIM carries out the assessment of the chemical formulation of the product and the verification of the conformity of all the substances used to manufacture the product with the requirements defined in Annex 1.* *ICIM proceeds, therefore, with the definition of the following actions:* ▪ *characteristics and number of samples to be examined;* ▪ *initial tests to be carried out defining the substances/parameters to be analysed against Annex 1;*
APPLICATION EXAMINATION REPORT
The conducted verification is recorded in the minutes reporting, where necessary, recommendations or non-conformities and indicating, for each applicable item, the suitability or not of said item (the points marked with the letters "NA" are not adequate and, if not properly resolved, entail a negative judgement on the safety of the equipment. The points marked with "A" (adequate) are considered compliant).
Other
NOTES

INITIAL AUDIT (IA)
METHOD TO BE APPLIED
The initial audit (IA) is carried out <u>only for CAT B products</u> as indicated in ICIM regulation 0003CR to ensure compliance with the requirements set forth in the normative documentation taken as reference and involves at least the verification: ▪ *of the design (project status and modifications), where applicable* ▪ *of the Manufacturing and Control Plan (checks in acceptance, intermediate finished products, storage, etc.), also by analysing the possible pollutants that remain on the product during the processing phases* ▪ *of the availability and adequacy of the means of production and control in production* ▪ *of traceability during production phases* ▪ *of non-conformity management* ▪ *of the quality records* ▪ *of measuring instruments and test and testing equipment management* ▪ *of the company laboratory and internal test procedures (if applicable)* *If the organization has different operating units for the manufacturing of the products to be certificate, the initial audit is carried out to each of them.* *During this phase the products to be tested are taken (sampling, see ITT)*
IA REPORT
The audit is drafted in a specific report, specifying, where necessary, recommendations or nonconformities and indicating the adequacy or inadequacy of each applicable item. The Organisation is given a copy of the report as a notification of the operation. The checklist is countersigned by the Organisation as acceptance of all issued findings.
Other
The Organisation can however initiate a review procedure following the procedure described in Regulation ICIM 0001CR.

INITIAL TESTS (ITT)

METHOD TO BE APPLIED

Type tests are performed on representative samples in external or internal accredited or qualified laboratories and periodically verified by ICIM.

Sampling

The selection and conformation of the testing sample/s representing the type subject to the Application must be such to allow the ITT to classify the product according to the reference standards.

As part of the Initial Audit, the GI performs the sampling for the Initial tests by choosing the samples for the initial tests from the current production and/or from the factory warehouse or from the retailer.

The type of samples representative of the current production to be taken at the factory or from the market to conduct the tests is defined by the series/family (product geometry, type of materials and any treatments that characterise the components, their Surface/Volume ratio).

During the Initial Tests, at least one (1) model is tested for each of the certified families following the sampling rules indicated below:

a. *The model that will be tested will be the one that (within the series/family) will have the most critical geometry in relation to the Surface/Volume ratio (the higher the S/V ratio, the more critical).*
b. *If it is not possible to clearly identify the most "critical" model through document analysis, samples of other variants will also be taken, which will be submitted to pre-tests (partial tests to analyse any critical issues).*

The tests to be carried out are those required to verify the parameters in Annex 1 relating to the individual materials that characterise the components of the product in contact with water intended for human consumption.

The initial tests, if carried out at the Organisation, are conducted in the presence of inspectors appointed by ICIM. The conducted audit is recorded on the report forms issued by ICIM. The testing laboratories must be accredited or qualified by ICIM according to the established procedures (normative reference UNI EN ISO IEC 17025). The individual analysis tests must be accredited in compliance with UNI EN ISO IEC 17025; if the same cannot be accredited, ICIM will intervene by qualifying them against the requirements of UNI EN ISO 17025. The purchase order relating to the initial tests must refer to the Annex to the RDA document relating to the tests to be carried out according to this scheme; where a contract is available between ICIM and the laboratory in charge of the tests, the aforementioned conditions must be indicated therein.

Objective of the tests

Verify that the materials used in products intended for contact with water intended for human consumption do not alter the chemical-physical characteristics of the water, as defined by Directive 98/83/EC.

Evaluation of results

ICIM asks the Laboratory in charge of the initial tests to indicate in the test reports the conformity of the result with the applicable legislation and accepts the decision-making rule on the basis of which this conformity is expressed.

If the results of the tests carried out on the individual materials making up the product fall within the range of the provisions of Annex 1, the product (Series / family) complies with this scheme.

In the event of negative results, the provisions of the ICIM 0003CR regulation apply.

Any "border line" values will result in the repetition of the test in the next visit after modifying the sampling already planned and if the test confirms the aforementioned values, an additional quotation will be prepared for its repetition.

ITT TEST REPORT

The conducted inspection is reported in the report forms of the laboratory qualified by ICIM, previously approved by ICIM. The outcome of the tests is reported on a special report stating if the test is positive or negative.

Other

NOTES

In the event of complaints or appeals related to the results of laboratory analyzes carried out both during the ITT and pursued in annual surveillance or renewal, ICIM will use an alternative laboratory for product reviews to the one that carried out the tests completed under the complaint. In this case, ICIM will use laboratories either accredited for specific tests by ACCREDIA (or other ILAC MRA body) or qualified by ICIM for specific tests, in case there are no accredited laboratories available.

ISSUING THE CERTIFICATION

OUTCOME
The technical documents submitted by the Organisation, the results of the audits and the outcome of the tests are evaluated. ***For the final assessment set forth in ICIM Regulation 0003CR is followed.*** *The findings issued are managed according to ICIM doc regulation 0003CR.* *In the event of a negative outcome, the Organisation can however initiate a review procedure following the procedure described in ICIM Regulation 0001CR.*
APPROVAL COMMITTEE
No changes with respect to the specific procedure of the Approval Committee. The proposer is the Technical Coordinator or the Competence Center Manager, the Decision Maker is the Technical Director assisted if necessary by a Technical Expert.
CERTIFICATE
After successful completion of previous interventions and after review and evaluation by the Approval Committee, ICIM draws up a Product Certificate in which the following is specified as a minimum: ▪ *Name and address of the Organisation,* ▪ *Identification of the Production Unit (also with code) if different from the Organisation,* ▪ *Certificate Number thus composed ICIM/ACQP/XXXXXX (XXXXXX certificate number)* ▪ *Product definition with possible description* ▪ *Normative reference document* ▪ *Date of issue and validity of the certificate (and current issue)* ▪ *Any conditions that the issue is subject to* *The Certificate is sent to the Organisation, after verification of complete payment of the operations carried out by ICIM.*
TRANSFER
The procedures for transferring the certificates are those described in doc. IAFMD02
TRADEMARK
The ICIM Mark must be applied according to the ICIM regulation 0260CR for product certifications. *In addition to the ICIM mark on the product there must be at least:* ▪ *trademark of the Organisation,* ▪ *item code,* ▪ *production date (also coded) or serial number (or batch)* ▪ *normative reference document.* *If the dimensions of the product do not allow the above information to be affixed to it, it must be stated on the primary packaging and on all the documentation supplied with the product, including shipping documents (see also Regulation 0003CR).*
Other
NOTES
All verification documents, as well as all documents in the check list and the certificates must be retained for the amount of time established in the ICIM procedures for products subject to voluntary certification, so that they can be made available to the public administration and ACCREDIA upon request formal.

ANNUAL MONITORING (AM)

METHOD TO BE APPLIED

Verification of the maintenance of the characteristics of the product against the present scheme takes place through at least one monitoring audit each year

Monitoring audit

Annual monitoring (AM) is carried out as indicated in ICIM regulation 0003CR to ensure maintenance of compliance with the requirements set forth in the normative reference document and entails the verification of at least:

- *the last inspection report*
- *complaints about the certified product*
- *the production statistics*
- *the design (design status and modifications)*
- *maintenance of the Manufacturing and Control Plan (checks at acceptance, intermediate finished products, storage, etc.)*
- *the maintenance of availability and adequacy of the means of production and control in production*
- *non-conformity management*
- *the quality records*
- *the marking on the product, packaging and documents*
- *the use of the ICIM Mark*

During the monitoring audit the products to be tested are taken (sampling)

Unplanned monitoring is possible as per ICIM regulation 0003CR for the products in CAT A as well as CAT B. If the organization has different operating units for the manufacturing of the products to be certificate, at least one of these will be checked during the validity of the certificate (5 years).

Monitoring Tests (MT)

The number of products representative of the current production to be taken at the factory, or from the market to conduct the surveillance tests is established according to the rule (Nm the serial number/families certified), rounded up to the higher number:

- $\sqrt{Nm} + 1$ *for Nm≥15;*
- $Nm/3$ *for Nm<15*

changing, where possible, the models to be tested within the family/series. The samples will be taken at the highest S/V ratio within the certified model.

Sample taking must be scheduled so that most models are tested within the 5-year certificate term. The objective of the tests is to verify the maintenance of the characteristics of the materials with respect to the ITT data.

The tests to be carried out are those identified in Annex 1 relating to the individual materials that characterise the components of the product in contact with water intended for human consumption.

The monitoring tests, if carried out at the Organisation, are conducted in the presence of inspectors appointed by ICIM. The conducted test is recorded on the report forms issued by ICIM. The testing laboratories must be accredited or qualified by ICIM according to the established procedures (normative reference UNI EN ISO IEC 17025).

The purchase order relating to surveillance tests must refer to the Annex to the RDA document relating to the tests to be carried out according to this scheme; where a contract is available between ICIM and the laboratory in charge of the tests, the aforementioned conditions must be indicated therein.

ICIM asks the Laboratory in charge of the tests to indicate in the test reports the conformity of the result with the applicable legislation and accepts the decision-making rule on the basis of which this conformity is expressed.

The outcome of the tests is recorded in a special report indicating whether the test is positive or negative. The test is positive if the products are within the range of the provisions of Annex 1. In the event of a negative result, what is indicated in 0003CR applies

Any "border line" values will lead to the repetition of the test in the next visit after modifying the sampling already planned and if the test confirms the aforementioned values, an additional quotation will be prepared for its repetition. In the event of a negative outcome of the tests, the Resolution Committee may decide to suspend the use of the trademark pending clarification from the Organization or to have the tests repeated on a new sampling (retries).

SV REPORT
The audit is drafted in a specific report, specifying, where necessary, recommendations or nonconformities and indicating the adequacy or inadequacy of each applicable item. Copy of the report and, if tests have been carried out, the test report is given to the Manufacturer as a notification of the operation. The checklist is countersigned by the Organisation as acceptance of all issued findings.
Other

NOTES
The Organisation can however initiate a review procedure following the procedure described in ICIM Regulation 0001CR.

CERTIFICATION VALIDITY

METHOD TO BE APPLIED
The validity of the Product Certificate is 5 (five) years. *The conditions for retaining the certificate are also indicated in ICIM regulation 0001CR and ICIM 0003CR.* *If the validity of the certificate is not renewed, the Organisation must immediately cease using the ICIM Mark, as per ICIM regulation 0001CR.*
Other

NOTES

RENEWAL

METHOD TO BE APPLIED
Renewal follows the procedure: *Renewal audit* *The renewal visit (VR) is carried out at the expiration of the certificate (five years) as indicated in the ICIM 0003CR regulation to ensure compliance with the requirements set out in the reference standard and laws.* *The certification renewal verification is performed at least 60 (sixty) days before expiration.* *During the renewal audit, at least the following points must be verified:* ▪ *last inspection report* ▪ *complaints about the certified product* ▪ *production statistics* ▪ *design (project status and modifications)* ▪ *Manufacturing and Control Plan (checks at acceptance, intermediate finished products, storage, etc.)* ▪ *availability and adequacy of the means of production and control in production* ▪ *traceability* ▪ *non-conformity management* ▪ *quality records* ▪ *installation, use and maintenance instructions* ▪ *marking on the product, packaging and documents* ▪ *use of the ICIM Mark* *During the renewal audit, ICIM takes the products to be tested (sampling)* *Renewal tests (RT)* *Renewal tests follow the same procedure as surveillance tests.* *ICIM asks the Laboratory in charge of the tests to indicate in the test reports the conformity of the result with the applicable legislation and accepts the decision-making rule on the basis of which this conformity is expressed.* *The test is positive if the products are within the range of the provisions of Annex 1.* *In the event of negative results, the provisions of the ICIM 0003CR regulation apply.* *Any "border line" values will result in the repetition of the test in the next visit after modifying the sampling already planned and if the test confirms the aforementioned values, an additional quotation will be prepared for its repetition.*
RV REPORT
The audit is drafted in a specific report, specifying, where necessary, recommendations or nonconformities and indicating the adequacy or inadequacy of each applicable item. Copy of the report and, if tests have been carried out, the test report is given to the Manufacturer as a notification of the operation. The checklist is countersigned by the Organisation as acceptance of all issued findings.
Other
When renewal is successfully granted, the Product Certificate is re-issued as per regulation 0003CR
NOTES
The Organisation can however initiate a review procedure following the procedure described in ICIM Regulation 0001CR.

CHANGES TO CERTIFICATION CONDITIONS

METHOD TO BE APPLIED
The organisation must inform ICIM of all changes, even minor ones, which it has made or intends to make to the product covered by the certificate. *ICIM examines said changes and decides whether:* *a) the change is not significant, in which case the Application is accepted without the need for additional inspections or tests; therefore it informs the Organisation that the certificate is valid with a supplement of the original examination document.* *b) the change is significant but not such to produce a new product, in which case verifications or additional tests are required; therefore the Organisation is informed that the certificate remains valid with a supplement of the original examination document issued upon the positive outcome of the additional inspections or tests.* *c) the change is significant to the extent that it produces a completely new product, in which case the Organisation is informed that the operations for Certification must be carried out in their entirety.*
Other *The Organisation can however initiate a review procedure following the procedure described in ICIM Regulation 0001CR.*
NOTES

COMMERCIAL CERTIFICATION EXTENSIONS

METHOD TO BE APPLIED
See regulation 0003CR
Other
NOTES

AUDITOR REQUIREMENTS

ADDITIONAL QUALIFICATIONS
As per the qualification procedure for inspectors, with a minimum specific experience for engineering graduates of 2 (two) years in the mechanic, chemistry, nuclear, aeronautics sector and comparable degrees (natural or biological sciences, food science and technology, physics, chemistry, etc.), optimal if specific to the design, manufacture, maintenance, inspection of products in the sector of products and components in contact with drinking water. For other technicians and non-graduates the minimum number of years of experience defined in the qualification procedure for the inspectors is always required in the sectors indicated above. *For technical experts, where necessary, the same level of minimum knowledge is required for inspectors with superior technical knowledge on specific topics related to a specific type of product in the field of products and components in contact with drinking water.*
ADDITIONAL CHARACTERISTICS
The GVI must be composed of one or more inspectors who can cover all the requirements indicated in the previous paragraph on "Additional Qualifications".
OTHER PERSONNEL IN CHARGE
▪ *Documentation Review (Coordinator competent for the specific scheme / sector)* ▪ *Final reviewer (Coordinator competent for the specific scheme / sector or if necessary; the Competence Center Manager; the Operation Manager; the Technical Director)* ▪ *Decision Maker, Technical Director*

ANNEX 1 (regulatory)

METHOD TO BE APPLIED
This certification scheme is based on the evaluation of possible negative effects on the quality of water intended for human consumption and on the health of the consumer deriving from the migration, into the water, of undesirable substances coming from the materials comprised in the product. The following tables contain the lists of materials considered suitable for use in products intended to come into contact with water intended for human consumption with any additional tests to be carried out on them. If a product contains one or more metallic materials not included in the list provided in the corresponding sheet, it will be necessary to perform the rig-test according to standard EN 15664 -1: 2008. ***In the case of products containing materials not included in the aforementioned sheets, the certification process cannot continue. In order for the material to be compliant with this scheme it is necessary to successfully follow the procedure set out in Annex 4.*** *Sheet 1 - METALLIC MATERIALS* *Sheet 2 - PLASTIC MATERIALS, NATURAL AND SYNTHETIC RUBBERS* *Sheet 3 - MATERIALS BASED ON HYDRAULIC BINDERS, VITREOUS ENAMELS, CERAMICS AND GLASS*
Other
NOTES

ANNEX 2 (informative)

METHOD TO BE APPLIED
At present there are no differences between the values indicated by ICIM in Annex 1 and those defined by Italian law (DM174). *Since at present the Ministerial Decree n. 174/2004 does not specifically regulate the following materials, used in the construction of systems for the treatment of water intended for human consumption:* *ion exchange resins* *Inert materials such as sand, quartzite, zeolite, and active materials such as granular coal,* *the following standards are used for the verification of compatibility with drinking water, following the instructions given by the manufacturer before using the product.* 1. *UNI EN 12873-3 - Influenza dei materiali sull'acqua destinata al consumo umano. Influenza dovuta alla migrazione parte 3: metodo di prova per resine a scambio ionico e adsorbenti* *2. Resolution ResAP (2004) 3 on ion exchange and adsorbent resins used in the processing of foodstuffs and Technical document No. 1: List of substances to be used in the manufacture of ion exchange and adsorbent resins used in the processing of foodstuffs (Version 3 – 28.01.2009)* *3. UNI EN 12902:2005 Materiali inorganici di supporto e filtrazione - metodi di prova*
Other
NOTES

ANNEX 3 (regulatory)

METHOD TO BE APPLIED

CONSTITUENT ELEMENTS OF THE DOSSIER TO REQUEST AUTHORISATION FOR USE OF A NEW MATERIAL OR A NEW CONSTITUENT

The dossier of the request for authorisation of a new constituent intended for the manufacture of material intended to come into contact with water intended for human consumption and which is not included in the sheets in this schedule must be established in accordance with the provisions of this Annex.

A dossier containing the following elements must be attached to each request for authorisation to use a new constituent. The scientific information is written in Italian. For original documents in foreign languages, a summary and a complete translation of the conclusions into Italian should be annexed.

I. Dossier type.

1. General information.

1.1. Name or company name and address of the applying organisation.

1.2. Designation and function of the constituent object of the application and indication of the materials or articles in which use is required.

1.3. Percentage of use of the constituent.

1.4. Presentation of the reasoning (technical or otherwise) to support the use of the constituent.

1.5. Indication of any risks to the environment.

1.6. Indication of any use in non-EU countries (authorisation references, copies of official authorisation documents accompanied by their translation into Italian).

2. Scientific information.

2.1. Chemical-physical information:

- *name of the constituent with any indication of the CAS number (Chemical Abstracts Service) if it exists and, if it is a defined compound, developed chemical formula expressed as far as possible according to the IUPAC international nomenclature rules;*
- *degree of purity of the constituent, nature and percentage of impurities likely to be present;*
- *methods of analysis used by the applicant to verify the purity, the research and the dosage of the constituent in the finished product and in the water and submission of the obtained results;*
- *results of preliminary migration assays conducted on the finished material processed in particular with the constituent to evaluate the possible effects on the organoleptic, physical, chemical and biological quality of the water in contact.*

2.2. Toxicological information:

a) The available documentation on known effects on humans;

b) According to the predictable migration level:

- *migration of the constituent in the water less than or equal to 50 micrograms per litre:*
- *three genotoxicity studies, a gene mutation test on bacteria, a gene mutation assay on mammalian cell cultures, and a chromosomal aberration assay on mammalian cell culture;*
- *migration of the constituent in water above 50 micrograms per litre:*
- *(90-day) oral toxicity study, three genotoxicity studies: a bacterial gene mutation assay, a gene mutation assay on mammalian cell cultures, and a chromosomal aberration assay on mammalian cell cultures.*

In the case of migration greater than 5000 micrograms per litre, additional experiments by ICIM may be required.

The results of the toxicological experiments must be accompanied by the verbal experience process or by precise and complete bibliographic references.

c) When the results of the preliminary tests provided for in this chapter justify it or when the chemical structure of the constituent creates suspicion of long-term toxicity, ICIM may request additional experiments.

II. Simplified dossier for constituents and materials authorised in a Member State of the European Union.

For constituents, not included in this decree, subject to an authorisation already granted by a member state of the European Union or by a member state that is a party to the agreement establishing the European Economic Area, the information folder contains:

1. General information;

1.1. Name or company name and address of the applying organisation;

1.2. Designation and function of the constituent object of the request and indication of the materials or articles in which its use is required.

1.3. Percentage of use of the constituent.

2. Chemical-physical information:

- *name of the constituent with any indication of the CAS number (Chemical Abstracts Service) if it exists and, if it is a defined compound, developed chemical formula expressed as far as possible according to the IUPAC international chemical nomenclature rules;*
- *degree of purity of the constituent, nature and percentage of impurities likely to accompany it;*
- *methods of analysis used by the applicant to verify the purity, the research and the dosage of the constituent in the finished product and in the water and submission of the obtained results;*
- *results of preliminary migration assays conducted on the finished material processed in particular with the constituent to evaluate the possible effects on the organoleptic, physical, chemical and biological quality of the water in contact.*

The above information dossier is definitively examined and evaluated within six months from the complete submission of the documentation.

3. Administrative information.

3.1. Extract of the national regulation (or official document) that defines the toxicological evaluation procedure, accompanied by a summary in Italian.

3.2. Opinion of the scientific body that carried out the toxicological evaluation of the constituent accompanied by their translation into Italian.

3.3. Reference of the official document issued by the Member State and copies of the official documents accompanied by their translation into Italian.

Following delivery of the documentation, ICIM evaluates the dossiers. If deemed compliant with the requirements of this scheme before issuing the certificate, however, ICIM will wait for approval by the Ministry of Health (or tacit acceptance after 3 months).

Other

Notes

The application and the dossier must also be sent to the Ministry of Health, for their approval. *The scientific information is written in Italian. For original documents in foreign languages, a summary and a complete translation of the conclusions into Italian should be annexed*

Sheet 1 - METALS AND METAL ALLOYS

I. METALS AND ALLOYS

a. COPPER ALLOYS

1. Copper and Zinc alloys

Constituents (% (m/m)):

Copper	Zinc
⩾ 57.0 %	The rest

impurities (% (m/m)):

Aluminium	Iron	Nickel	Lead	Tin
⩽ 0.1 %	⩽ 0.5 %	⩽ 0.2 %	⩽ 0.2 %	⩽ 0.5 %

Other impurities: each <0.02%

Accepted alloys:

designation	Product classes
CW509L (CuZn40)	A
CW510 L (CuZn42)	A

2. Copper-zinc-arsenic alloys

Constituents (% (m/m)):

Copper	Zinc	Arsenic
⩾ 61.0 %	The rest	0.02 % - 0.15 %

Impurities (% (m/m)):

Aluminium	Iron	Manganese	Nickel	Lead	Tin
⩽ 0.1 %	⩽ 0.5 %	⩽ 0.3 %	⩽ 0.3 %	⩽ 0.2 %	⩽ 0.5 %

Other impurities: each <0.02%

Accepted alloys

designation	Product classes
CW511L (CuZn38As)	A

3. **Copper-zinc-arsenic-aluminium alloys**

Constituents (% (m/m)):

Copper	Zinc	Arsenic	Aluminium
⩾ 61.0%	The rest	0.02 % - 0.15 %	0.2 % - 1.0 %

Impurities (% (m/m)):

Iron	Manganese	Lead	Tin
⩽ 0.5 %	⩽ 0.1 %	⩽ 0.2 %	⩽ 0.3 %

Other impurities: each <0.02%

Accepted alloys

Designation	Product classes
CuZn35Al-C	A

4. **Copper-zinc-lead alloys**

Constituents (% (m/m)):

Copper	Zinc	Lead
⩾ 57.0 %	The rest	0.2 % - 3.5 %

Impurities (% (m/m)):

Aluminium	Iron	Nickel	Silicon	Tin
⩽ 0.3 %	⩽ 0.5 %	⩽ 0.2 %	⩽ 0.2 %	⩽ 0.5 %

Other impurities: each <0.02%

Accepted alloys

designation	Product classes
CW617N (CuZn40Pb2) **CW612N (CuZn39Pb2)** **CW614N (CuZn39Pb3)** **CW603N (CuZn36Pb3)**	A

5. Copper-zinc-lead-arsenic-aluminium alloys

Constituents (% (m/m)):

Copper	Zinc	Lead	Arsenic	Aluminium
⩾ 61.0 %	The rest	0.2 % - 2.2 %	0.02 % - 0.15 %	0.02 % - 1.0 %

Impurities (% (m/m)):

Iron	Manganese	Nickel	Tin
⩽ 0.5 %	⩽ 0.1 %	⩽ 0.2 %	⩽ 0.5 %

Other impurities: each <0.02%

Accepted alloys

designation	Product classes
CC770S (CuZn36Pb-C) **CW626N (CuZn33Pb1.5AlAs)** **CW625N (CuZn35Pb1.5AlAs)**	A

6. Copper-zinc-tin-lead-nickel alloys

Constituents (% (m/m)):

Copper	Tin	Zinc	Lead	Nickel
The rest	4.0 % - 13.0 %	4.0 % - 6.5 %	0.2 % - 3.0 %	0.1 % - 0.6 %

Impurities (% (m/m)):

Iron	Phosphorus	Sulphur	Antimony
⩽ 0.30 %	⩽ 0.04 %	⩽ 0.04 %	⩽ 0.10 %

Other impurities: each <0.02%

Accepted alloys

Designation	Product classes
CC499K (CuSn5Zn5Pb2-C)	A

7. **Copper alloys containing silicon-high zinc content**

Constituents (% (m/m)):

Copper	Zinc	Silicon	Phosphorus
60.0 % - 80.0 %	The rest	0.5 % - 5.5 %	0.01 % - 0.3 %

Impurities (% (m/m)):

Aluminium	Iron	Manganese	Nickel	Lead	Tin
⩽ 0.1 %	⩽ 0.5 %	⩽ 0.05 %	⩽ 0.2 %	⩽ 0.1 %	⩽ 0.5 %

Other impurities: each <0.02%

Accepted alloys

designation	Product classes
CW724R (CuZn21Si3P) **CC768S (CuZn21Si3P)**	A

8. Copper alloys containing silicon-high copper content

Constituents (% (m/m)):

Copper	Zinc	Silicon	Phosphorus	Manganese
⩾ 80.0 %	Remainder	0.5 % - 5.5 %	0.01 % - 0.3 %	0.01 % - 0.2 %

Impurities (% (m/m)):

Aluminium	Iron	Nickel	Lead	Tin
⩽ 0.3 %	⩽ 0.5 %	⩽ 0.1 %	⩽ 0.1 %	⩽ 0.5 %

Other impurities: each <0.02%

Accepted alloys

designation	Product classes
CuZn10Si4MnP	A

II. COPPER

9. Copper

Constituents (% (m/m)):

Copper	Phosphorus
⩾ 99.9 %	0.015<**P**<0.04%

Impurities (% (m/m)):

Total-rest
⩽ 0.06 %

Other impurities: ≤ 0.02 %

Accepted alloys

Designation	Product classes
CW024A (Cu-DHP)	A, B

- **Pipes and fittings in copper with internal tin coating**

Accepted alloys

Designation	Product classes
CW024A (Cu-DHP) with tin coating 1 µm thick	A and B

Constituents of the Tin coating (% (m/m)):

Tin	Copper
> 90 %	<10 %

Impurities in Tin coating (% (m/m)):

Arsenic	Bismuth	Cadmium	Chromium	Nickel	Lead	Antimony
⩽ 0.01 %	⩽ 0.01 %	⩽ 0.01 %	⩽ 0.01 %	⩽ 0.01 %	⩽ 0.01 %	⩽ 0.01 %

III. CARBON AND CAST IRON STEEL

Hot-dip galvanised carbon steel (coating according to EN 10240 - coating quality A.1)

designation	Product classes
Galvanised carbon steel	A and B

Constituents of zinc coating (% (m/m):

Zinc
≥ 99.5 %

Impurities of zinc coating (% (m/m):

Arsenic	Bismuth	Cadmium	Chromium	Lead	Antimony
≤ 0.02 %	≤ 0.01 %	≤ 0.01 %	≤ 0.02 %	≤ 0.05 % [1)] ≤ 0.1 % [2)]	≤ 0.01%

(1) Pipes

(2) a) taps, fittings, appliances and pumps; b) components in which the surface in contact with water does not exceed 10% of the total surface of the components indicated in a)

Maximum total of other impurities considered toxic: ≤ 0.05%

Coated carbon steel

designation	Product classes
Coated carbon steel	B

- **Pipes in coated carbon steel**

Maximum content of other constituents:

Chromium	Nickel	Molybdenum
≤0.3 %	≤0.3 %	≤0.1 %

Maximum impurity content:

Arsenic	Cadmium	Lead	Antimony
≤ 0.02 %	≤ 0.02 %	≤ 0.02 %	≤ 0.02%

The coatings must comply with the standards indicated for the various materials used.

- **Coated carbon steel components.**

Maximum content of other constituents:

Chromium	Nickel	Molybdenum
≤1 %	≤0.5 %	≤ 1 %

Maximum impurity content:

Arsenic	Cadmium	Lead	Antimony
≤ 0.02 %	≤ 0.02 %	≤ 0.02 %	≤ 0.02%

The coatings must comply with the standards indicated for the various materials used.

Cast iron

- **Cast iron pipes with organic material coating (product classes A and B)**

The coatings must comply with the standards indicated for the various materials used.

- **Uncoated cast iron components (class A only)**

Constituents (% (m/m)):

Iron	Carbon	Chromium	Molybdenum	Nickel
		≤ 1.0 %	≤ 1.0 %	≤ 0.5 %

Impurities (% (m/m)):

Arsenic	Cadmium	Lead	Antimony
≤ 0.02 %	≤ 0.02 %	≤ 0.02 %	≤ 0.02 %

Accepted alloys

designation	Group Products
cast iron	A

IV. STAINLESS STEEL
The stainless steels provided for by law concerning materials and articles intended for contact with food referred to in (It.) Ministerial Decree of 21 March 1973 and subsequent updates can be used, if in the aforementioned legislation use is not expressly forbidden when in contact with water and meets the conditions, limitations and tolerances for use therein.

V. ALUMINIUM
Aluminium items must fulfil the requirements of (It.) Presidential Decree n. 777 of 23 August 1982, and (It.) Legislative Decree 108 of 25 January 1992 and (It.) Decree of the Ministry of Health no. 76 of 18 April 2007.

Sheet 2 - PLASTIC MATERIALS, NATURAL AND SYNTHETIC RUBBERS

Plastic, including painting, coatings, membranes can be manufactured exclusively starting from the constituents indicated in Reg. EC no. 10/11. Furthermore, the articles prepared from the aforementioned constituents must not yield substances considered harmful to health, such as certain monomers, low molecular weight compounds, intermediates, catalysts, from the constituents indicated below: solvents emulsifying agents.

Scraps and waste from the production of plastics intended for contact with water for human consumption, which have not been used or otherwise contaminated, are considered suitable for applications intended for contact with water for human consumption and can therefore be transformed again on-site to manufacture new products.

The use of materials from after-use recovery activities is prohibited.

2 A Composition of plastic

The composition of plastic intended for contact with water for human use must comply with the provisions of Regulation 10/2011 concerning plastic and articles intended to come into contact with foodstuffs and subsequent updates and amendments.

Checks to be carried out on the finished product:

- control of the global migration, of the specific migration (if indicated for the single constituents) according to the limits indicated by Reg. EC no. 10/11
- control of the migration of dyes according to the methods set out in Annex III C of the Ministerial Decree of 21 March 1973.

2 B Composition of elastomers

For the production of elastomers intended for contact with water for human use the substances approved by (It.) Decree 21/03/73 and subsequent amendments, as well as the substances authorised by other Member States in accordance with the provisions of current legislation can also be used. the substances reported in Reg.10/2011 and subsequent updates and amendments intended exclusively for the plastics industry which may also be used in the production of elastomeric items, subject to verification of the methods and relative limits.

Checks to be carried out on the finished product:

- control of the global migration, of the specific migration (if indicated for the single constituents) according to the limits indicated by (It.) Ministerial Decree 21 March 1973.
- control of the migration of dyes according to the methods set out in Annex III C of the Ministerial Decree of 21 March 1973.

Sheet 3 - MATERIALS BASED ON HYDRAULIC BINDERS, VITREOUS ENAMELS, CERAMICS AND GLASS

I. Hydraulic binder-based materials

- **Hydraulic binders**

- cement which conforms with standard EN 197-1 and standard EN 14216.
- masonry cement which conforms with standard EN 413-1,
- natural hydraulic lime which conforms with standard EN 459-1
- hydraulic binders with a calcium aluminate base also including aluminate cement[1] which conforms with EN 14647 standard.

In any case hydraulic binders covered by "European Technical Assessment" can be included.

- **Aggregates**

- aggregates with density greater than 2000 kg/m3 and recycled aggregates with density greater than 1500 kg/m3 compliant with standards EN 12620 and UNI 8520 Parts 1 and 2.
- aggregates with a density of less than 2000 kg/m3 (light aggregates) compliant with EN 13055-1.
- aggregates for the preparation of mortars that meet the requirements of standard EN 13139.

- **Additives**

- inorganic additives according to EN 934-2, 3, 4 and 5.
- additives not included in EN 934-2, 3, 4, 5 but complying with UNI 11104 (editor's note: under revision) which constitutes the national application document of EN 206 "Concrete - specification, performance, production and conformity".

- **Admixtures**

- Admixtures complying with EN 1008 and to drinking water standards.

- **Fibres**

- Metal fibres

  cast iron and steel fibres complying with standard EN 14889-1 that respect the compositional requirements of the metals they come from

- Non-metallic mineral fibres v. additional constituents
- Organic fibres (For the use of fibres in concrete, reference is made to standard EN 14889-2)
  A) natural cellulosic fibres,
  B) polyolefin fibres,
  C) polyacrylonitrile fibres,
  D) polyvinyl alcohol fibres, polyamide and linear polyester fibres under the condition that they meet the requirements for organic materials

[1] Italian legislation (Ministerial Decree 14 January 2008 "*Approval of new technical standards for construction*") prohibits the use of calcium aluminate cement in structural concrete

- Additional constituents

A) Additional constituents for concrete (Additions, Fillers and Pigments)

1) Additions

- Type I additions: essentially inert, include fillers and pigments;
- Type II additions
  - fly ash according to EN 450-1,
  - silica fumes according to EN 13263-1
  - and the high-furnace slag conforming to EN 15167-1.

Furthermore, additional constituents authorised by the regulation on materials and articles in contact with foodstuffs can be used.

2) Fillers in compliance with EN 12620 and EN 13055.
3) Pigments comply with EN 12878.

B) *Additional organic constituents*

The additional organic constituents manufactured with the constituents authorised by Commission Regulation (EU) 10/2011 may be used for plastic materials and articles intended to come into contact with foodstuffs and national regulations for contact with drinking water.

II. Vitreous enamels, ceramics and glass

Vitreous enamels must meet the standards set forth in Article 2, point c of Legislative Decree no. 108 of 25 January 1992. Ceramics must meet the specific standards of the Ministerial Decree of 4 April 1985 "Regulation of ceramic articles intended to come into contact with foodstuffs".

Glass articles must meet the provisions of ministerial decree of 21 March 1973

Miscellaneous notes