INFORMATIVE CIRCULAR

Ref. DC2026MGR001 **Milan**, 07-01-2026

To all accredited and applicant PRD Certification Bodies
To the associations of Conformity Assessment Bodies
To the Assessors/Experts of DC Department

SUBJECT: Information Circular DC No. 55/2025 – Provisions regarding accreditation, PRD scope, pursuant to ISO/IEC 17065:2012, for the certification of products in contact with water intended for human consumption, hereinafter also referred to as "drinking water", in accordance with Directive (EU) 2020/2184 (DWD).

Introduction

Directive (EU) 2020/2184, transposed into Italian law by Legislative Decree No. 18/2023, as amended by Legislative Decree No. 102/2025 (which entered into force on 19 July 2025), lays down harmonised requirements for the quality of water intended for human consumption. In particular, it introduces specific provisions for the conformity assessment of products in contact with water intended for human consumption, hereinafter also referred to as drinking water. Among the main innovations introduced are also chemical reagents and active and passive filtering materials (hereinafter "ReMaF"), used in treatment processes and in technological processes connected with the preparation and distribution of drinking water.

Characteristics of the Scheme

The certification scheme for products in contact with drinking water is based on the accreditation standard ISO/IEC 17065:2012 and requires certification by Notified Certification Bodies, in accordance with the conformity assessment modules defined by Delegated Regulation (EU) 2024/370 and the related implementing acts. Materials and products must comply with the hygiene and safety requirements set out by European legislation, including conformity with positive lists and harmonised marking.

For products in contact with drinking water, certification is mandatory and must be issued by Notified Certification Bodies designated by the Member States, accredited according to the standard ISO/IEC 17065:2012. The accreditable conformity assessment modules include Module B (EU Type Examination) and Module D (Production Process Quality Assurance), depending on the product's level of risk.

The certification of ReMaF is also based on the accreditation standard ISO/IEC 17065:2012. This certification, which does not apply to disinfectant ReMaF, biocides, or PMC, is voluntary and not notified, but it is mandatory

to obtain ReMaF authorisation from the National Water Safety Centre (CeNSiA), as it is a nationally applicable certification under Article 11 and Annex IX of Legislative Decree 18/2023, as amended by Legislative Decree 102/2025.

It should be noted that the compliance of ReMaF will be verified based on the technical requirements defined in Sections B, C, and D of Annex IX of Legislative Decree 18/2023, as integrated and amended by Legislative Decree 102/2025**. <u>However, the verification procedures are yet to be defined and will be developed within a technical working group composed of representatives from ACCREDIA, CeNSiA, the National Institute of Health, the Ministry of Health, and the CAB Associations, to be completed by 2026.</u>**

<u>The accreditation procedures for ReMaF will therefore be communicated at a later date through an update to this circular.</u>

Regulatory References for Certification

- Directive (EU) 2020/2184 on the quality of water intended for human consumption.

Delegated Regulations

- Delegated Regulation (EU) 2024/369: Procedure for the inclusion or removal from the European positive lists of starting substances, compositions, and constituents;
- Delegated Regulation (EU) 2024/370: Conformity assessment procedures for products in contact with drinking water and rules for the designation of Conformity Assessment Bodies;
- Delegated Regulation (EU) 2024/371: Harmonised specifications for the marking of products in contact with drinking water.

Implementing Decisions

- Implementing Decision (EU) 2024/365: Rules for the application of testing methodologies and the acceptance of starting substances, compositions, and constituents to be included in the European positive lists;
- Implementing Decision (EU) 2024/367: Establishment of the European positive lists of authorised starting substances, compositions, and constituents;
- Implementing Decision (EU) 2024/368: Rules for the application of procedures and testing methods for the acceptance of final materials used in products in contact with drinking water.

National Legislation

- Legislative Decree 18/2023: Implementation of Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption;
- Legislative Decree 102/2025: Supplementary and corrective provisions to Legislative Decree 18 of 23 February 2023, implementing Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption.

Accreditation Process

A condition for a Certification Body to be accredited is compliance with:

- the standard ISO/IEC 17065:2012;
- the requirements relating to notified bodies under Delegated Regulation (EU) 2024/370;
- the current ACCREDIA Regulation RG-01 for the accreditation of Certification, Inspection, Validation, and Verification Bodies;
- the current ACCREDIA Regulation RG-01-03 for the accreditation of Product/Service/Process Certification Bodies;
- the EA-2/17 M document currently in force.

A	Certification Body already accredited under the ISO/IEC 17065:2012 Scheme	• Document review of 1 man/day • Assessment at the Certification Body's offices: minimum 1 man/day. • 1 witness assessment for the requested module, with a minimum duration of 0.5 man/day, to be carried out during the Certification Body's first activity and, in any case, within 18 months of the relevant CSA resolution.
B	Certification Body not yet accredited to ISO/IEC 17065:2012, but accredited for other accreditation schemes.	• Document review of 1 man/day • Assessment at the Certification Body's offices: minimum 2 man/days. • 1 witness assessment for the requested module, with a minimum duration of 0.5 man/day, to be carried out during the first activity performed by the Certification Body and in any case within 18 months of the resolution by the competent CSA.
C	Certification Body not yet accredited in any scheme	• Document review of 1 man/day • Assessment at the Certification Body's offices: minimum 4 man/days. • 1 witness assessment for the requested module, with a minimum duration of 0.5 man/day, to be carried out during the Certification Body's first activity and, in any case, within 18 months of the resolution by the competent CSA.

Organisations intending to start accreditation activities must submit DA-00 and DA-04 in the current version, downloadable from the ACCREDIA website, together with all the required documents.

A technical quotation will then be provided by ACCREDIA, detailing all the planned accreditation activities.

For the notified scope, accreditation is a prerequisite for obtaining authorisation from the Ministry of Health and notification by the Ministry of Enterprises and Made in Italy (MIMIT).

For the testing activities required by Directive (EU) 2020/2184 for product certification purposes, it is recommended that Conformity Assessment Bodies use laboratories accredited under the ISO/IEC 17025 standard by a body that is a signatory to the IAF (International Accreditation Forum) and ILAC (International Laboratory Accreditation Cooperation) multilateral agreements. Only if accredited tests are not available should these tests be assessed as provided for under ISO/IEC 17065:2012.

Maintenance of accreditation

For the maintenance of accreditation throughout the entire accreditation cycle, except in particular situations (e.g., handling of complaints and reports, changes to the certification scheme, changes in the structure of the Organisation…), the following assessments will be conducted:

- 1 annual surveillance assessment with sampling of files for modules B and D;
- at least one witness assessment per module during the accreditation cycle.

Best regards.

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