ACCREDIA
ENTE ITALIANO DI ACCREDITAMENTO

Certification and Inspection Department

ACCREDIA approach to accreditation finalized to notifications regarding CE marking and consequent requirements for CABs applying for this type of Accreditation

DT-01-DC

REVISION
02

DATE
22-05-2025

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NOTE *The present document represents the English version of the document under reference at the specified revision. In case of conflict, the Italian version will prevail.*

PREPARATION
Management System Representative

APPROVAL
The Department Director

AUTHORIZATION
The General Director

APPLICATION DATE
09-06-2025

Contents

1. Introduction

The purpose of this document is to outline the rationale and implementation procedures for the accreditation of Conformity Assessment Bodies (CABs), aimed at enabling the issuance of Authorisations by the Competent Authorities for the purpose of notification to the European Commission and subsequent registration in the NANDO (New Approach Notified and Designated Organisations) database of Notified Bodies (NBs).

The approach is based on the "Blue Guide on the Implementation of EU Product Rules 2022" – Annex VI, paragraph 4 (the so-called "Blue Guide"), on document EA 2/17 M:2020, and on the provisions issued by the National Notifying Authorities.

2. Reference acronyms

- CAB: Conformity Assessment Body[1];
- NB: Notified Body;
- NAB: National Accreditation Body;
- NA: National Notifying Authority;
- CSA AR: Sectoral Committee for the Accreditation of Regulated Activities
- CSA CPR: Sectoral Committee for the Accreditation of Construction Products;
- CSA AG: Sectoral Committee for the Accreditation of Agri-food Products.
- CSA CI: Sectoral Accreditation Committee of Certification and Inspection

3. References

Below are the documents containing the reference requirements that ACCREDIA applies in the context of accreditations for the purposes of authorizations/notifications:

- Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008;
- Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008;
- Blue Guide on the Implementation of EU Product Rules 2022;
- Document EA 2/17 M:2020;
- Level 3 standards (according to document EA 1/06), such as: ISO/IEC 17021-1, ISO/IEC 17024, ISO/IEC 17065, ISO/IEC 17020, ISO/IEC 17029, ISO/IEC 17025.
- Applicable ACCREDIA Technical Circulars as per document LS-14;
- EA Resolutions as per document EA-INF 17, in currently revision and available at the following link: https://european-accreditation.org/wp-content/uploads/2020/01/EA-INF_17.pdf;
- IAF/ILAC/EA interpretative/implementing guides for the standards, where available;

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1 In this document, the term refers to Certification, Inspection, Validation and Verification Bodies.

- Provisions of the National Notifying Authority;
- Guidance/clarifications provided in the EA Accreditation for Notification (AfN) Project, in the available versions.

The general ACCREDIA Regulations issued for the accreditation of Certification, Inspection, Validation and Verification Bodies also apply, such as[2]:

- RG-01 General Part;
- RG-01-01 “Regulation for the accreditation of management system certification bodies”;
- RG-01-02 “Regulation for the accreditation of Certification Bodies of Persons”;
- RG-01-03 “Regulation for the accreditation of product/service/process certification bodies”;
- RG-01-04 “Regulation for the accreditation of Inspection Bodies”;
- RG-01-05 “Regulation for the accreditation of verification and validation bodies”.

For each of the mentioned documents, the latest valid revision applies. ACCREDIA documents can be freely downloaded from the documents section of the ACCREDIA website.

All documents listed in LS-02 (ISO/IEC 17021, ISO/IEC 17024, and ISO/IEC 17065), LS-03 (ISO/IEC 17020), LS-04 (ISO/IEC 17025), and LS-12 (ISO/IEC 17029) also apply.

4. Applicable standards under the various directives

With the release of the 2020 revision of the mandatory document EA 2/17 (in force for all CABs as of 17 April 2023), EA revised the previous “Approach 1+” by identifying the harmonised standards used for the accreditation of CABs for each module.

The details are provided in Annex A of the aforementioned document, which is reproduced below:

Table 1: Preferred Standards for <u>Aligned</u> Directives/Regulations and related Conformity Assessment Activities:

Module		**Other references equivalent to this module**	**Preferred Standard**	**Exceptions**
A1	Internal production control plus supervised product testing		ISO/IEC 17020	

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[2] “For AVCP system 3, as set out in Regulation (EU) 305/2011 (CPR), reference is made to the ACCREDIA regulations applicable to the ISO/IEC 17025 scheme for testing laboratories”

Module		Other references equivalent to this module	Preferred Standard	Exceptions
A2	Internal production control plus supervised product checks at random intervals		ISO/IEC 17020	Measuring Instruments Directive No. 2014/32/EU: ISO/IEC 17065
B	EU Type Examination	Machinery Directive 2006/42 EC- Annex IX; In vitro diagnostic medical devices (IVDMD) Directive No 98/79/EC Annex V; Active implantable medical devices (AIMD) Directive No 90/385/EEC Annex III	ISO/IEC 17065	
C	Conformity to EU-type based on internal production control		ISO/IEC 17020 (SPV) ISO/IEC 17065 (HWB)	Module C does not require a NB with the exception of: Simple Pressure. Vessels Directive No. 2014/29/EU (SPV). Hot-Water Boilers Directive No. 92/42/EEC (HWB)
C1	Conformity to EU-type based on internal production control plus supervised product testing		ISO/IEC 17065	Recreational craft and personal watercraft (RCD) Directive no 2013/53/EU: ISO/IEC 17020
C2	Conformity to EU-type based on internal production control plus supervised product checks at random intervals		ISO/IEC 17065	

Module		Other references equivalent to this module	Preferred Standard	Exceptions
D	Conformity to EU-type based on quality assurance of the production process		ISO/IEC 17065	
D1	Quality assurance of the production process		ISO/IEC 17065	
E	Conformity to EU-type based on product quality assurance		ISO/IEC 17065	
E1	Quality assurance of final product, inspection and testing		ISO/IEC 17065	
F	Conformity to EU-type based on product verification	Lifts and safety components for lifts Directive No: 2014/33/EC Annex V Final Inspection	ISO/IEC 17065	Lifts and safety components for lifts Directive No: 2014/33/EC ISO/IEC 17020
F1	Conformity based on product verification		ISO/IEC 17065	
G	Conformity based on unit verification	Noise emission in the environment by equipment for use outdoors Directive No 2000/14/EC Annex VII	ISO/IEC 17065	
H	Conformity based on full quality assurance	Machinery Directive No 2006/42/EC Annex X; Noise emission in the environment by equipment for use outdoors Directive No 2000/14/EC Annex VIII In vitro diagnostic medical devices (IVDMD) Directive No 98/79/EC Annex IV; Active implantable medical devices (AIMD) Directive No 90/385/EEC Annex II;	ISO/IEC 17021-1	

Module		Other references equivalent to this module	Preferred Standard	Exceptions
H1	Conformity based on full quality assurance plus design examination		ISO/IEC 17065	

Table 2: Preferred Standards for Non-Aligned Directives/Regulations and Conformity Assessment Activities, where there is no direct equivalent in the NLF Modules:

Directive	Conformity assessment procedure	Preferred Standard
2014/68/EU Pressure equipment (PED)	Approval of NDT personnel	ISO/IEC 17024
	Approval of Permanent Joining Personnel	ISO/IEC 17024
	Approval of Permanent Joining Procedures	ISO/IEC 17020
	European Approval of Materials	ISO/IEC 17065
Construction Product Regulation (EU) No 305/2011 (CPR)	System 1	ISO/IEC 17065
	System 1+	ISO/IEC 17065
	System 2+	ISO/IEC 17065
	System 3	ISO/IEC 17025
	System 3+	ISO/IEC 17029
98/79/EC In vitro diagnostic medical devices (IVDMD)	Annex III EC Declaration of Conformity	ISO/IEC 17065
	Annex VI EC Verification	ISO/IEC 17065

Directive	Conformity assessment procedure	Preferred Standard
	Annex VII EC Declaration of Conformity (Production quality assurance)	ISO/IEC 17065
90/385/EEC Active implantable medical devices (AIMD) modified by Directive No 93/42/EEC, 93/68/EEC and 007/47/EC	Annex IV EC Verification	ISO/IEC 17065
	Annex V EC Declaration of Conformity to Type (Assurance of production quality)	ISO/IEC 17065
93/42/EEC Medical Devices	Annex IV EC verification	ISO/IEC 17065
	Annex V EC Declaration of Conformity - Production Quality Assurance	ISO/IEC 17065
	Annex VI EC Declaration of Conformity – Product Quality Assurance	ISO/IEC 17065
2000/14/EC Noise emission in the environment by equipment for use outdoors	Annex VI Internal control of production with assessment of technical documentation and periodical checking	ISO/IEC 17065
2010/35/EU Transportable pressure equipment (TPED)	Type Approval	ISO/IEC 17020:2012 (except clause 8.1.3)
	Supervision of manufacture and Initial Inspection and Tests	ISO/IEC 17020:2012 (except clause 8.1.3)

Directive	Conformity assessment procedure	Preferred Standard
	Periodic Inspections, Intermediate Inspections and Exceptional Inspection	ISO/IEC 17020:2012 (except clause 8.1.3)
	Surveillance of the inhouse inspection service	ISO/IEC 17020:2012 (except clause 8.1.3)
	Reassessment of conformity	ISO/IEC 17020:2012 (except clause 8.1.3)
2013/53/EU Recreational craft and personal watercraft (RCD).	Post construction assessment	ISO/IEC 17065
Railways Interoperability Directive (EU) 2016/797 (IOD)	All modules in accordance with Decision 2010/713/EU in conjunction with the ERA Mandatory Technical Document 000MRA1044	ISO/IEC 17065

Annex B of the same EA document also identifies, for each harmonised standard, the additional requirements and procedures necessary to assess the competence of the CABs.

Table 3: Conformity Assessment Standards for Accreditation for Notification purposes incl. Applicable Additional Requirements:

Module	Description	EN ISO/IEC 17065	EN ISO/ IEC 17020	EN ISO/IEC 17021-1	EN ISO /IEC 17025
A	Internal production control	N/A	N/A	N/A	N/A
A1	Internal production control plus supervised product testing	1+t	* 1+t+cd		1+cd
A2	Internal production control plus supervised product checks at random intervals	1+t	* 1+t+cd		1+cd

Module	Description	EN ISO/IEC 17065	EN ISO/ IEC 17020	EN ISO/IEC 17021-1	EN ISO /IEC 17025
B	EC type examination	*1+t+pk	1+t+cd		
C	Conformity to type based on internal production control	N/A	N/A	N/A	N/A
C1	Conformity to type based on internal production control plus supervised product testing	*1+t+pk	1+t+cd		1 + cd + pk
C2	Conformity to type based on internal production control plus supervised product checks at random intervals	* 1 + t + pk	1 + t + cd		1 + cd + pk
D	Conformity to type based on quality assurance of the production process	* 1 + qa	1 + qa	1 + pk	
D1	Quality assurance of the production process	* 1 + qa	1 + qa	1 + pk	
E	Conformity to type based on product quality assurance	* 1 + qa	1 + qa	1 + pk	
E1	Quality assurance of final product, inspection and testing	* 1+ qa	1 + qa	1 + pk	
F	Conformity with type based on product verification	* 1 + t + pk	1 + t + cd		
F1	Conformity based on product verification	* 1 + t + pk	1 + t + cd		
G	Conformity based on unit verification	* 1 + t + pk	1 + t + cd		

Module	Description	EN ISO/IEC 17065	EN ISO/ IEC 17020	EN ISO/IEC 17021-1	EN ISO /IEC 17025
H	Conformity based on full quality assurance	1 + qa	1 + qa	* 1 + pk	
H1	Conformity based on full quality assurance plus design examination	* 1 + qa	1 + qa	1 + pk	

Table 4: Conformity Assessment Standards for Accreditation for Notification purposes incl. Applicable Additional Requirements in the Area of the Construction Products Regulation:

AVCP-system	Description	EN ISO/IEC 17065	EN ISO/IEC 17025	EN ISO/ IEC 17029
1+	determination of the product-type, initial inspection of factory production control, continuous surveillance of factory production control, audit-testing of samples	* 1 + t + pk		
1	determination of the product-type, initial inspection of factory production control, continuous surveillance of factory production control	* 1 + t + pk		
2+	initial inspection of factory production control, continuous surveillance of factory production control	* 1 + pk		
3	determination of the product-type		1	
3+	control of environmental sustainability assessment			1

Key:

* Indicates for the corresponding module the preferred standard that shall be used whenever possible (refer to annex A for details of specific legislation).

1 The possible Harmonised Standards used for accreditation.

+ Additional applicable requirements of the other pertaining Harmonised Standards used for assessing the NB, as relevant to the situation.

T Additional applicable requirements of EN ISO/IEC 17025 if **t**esting is required. To this end fulfilment of the applicable requirements of clause 6 and 7 (except 7.9) in EN ISO/IEC 17025:2017 shall be demonstrated.

cd **C**apability of and procedures for judging and **d**eciding based on results of tests and/or inspections, if the essential requirements are fulfilled and/or the Harmonised Standards have been applied when required. To this end, fulfilment of clauses 4.1.2, 4.1.3, 7.5 and 7.6 in EN ISO/IEC 17065:2012 shall be demonstrated.

pk Ability – based on **p**roduct **k**nowledge - to make professional judgments related to product requirements where required. To this end fulfilment of clauses 6.1.2, 6.1.3 and 6.1.6 to 6.1.10 in EN ISO/IEC 17020:2012 shall be demonstrated.

qa Ability to assess and approve manufacturer's **q**u**a**lity systems where required. To this end, fulfilment of clauses 7.1.1, 7.1.2, 7.2.4, 7.2.5, 7.2.8, 7.2.10 and 9.1 to 9.4 and 9.6 in EN ISO/IEC 17021-1:2015 shall be demonstrated.

For the definition of the term 'competence', reference should instead be made to the EN ISO 19011 standard (the ability to apply knowledge and skills to achieve intended results), to ISO/IEC 17021 (demonstrated ability to apply knowledge and skills), to the Ministerial Directive of 13 December 2017 – Applications for authorisation and notification of conformity assessment bodies, as well as to any provisions contained in relevant transposition and/or implementing decrees.

It should be noted, finally, that if the Notifying and/or Regulatory Authority has officially established (e.g., through the publication of a Decree), with regard to an aligned directive/regulation, that the preferred standard is not to be applied but instead a different one, and provided that, for an aligned directive/regulation/conformity assessment module, the nationally established standard complies with Table 3 of Annex B of document EA 2/17, the 1+ approach shall be applied accordingly.

5. Operational Procedures and Verification Activities Conducted by ACCREDIA

For the acquisition, extension, maintenance (including renewal) of accreditation for subsequent 'Authorisation' and 'Notification', the provisions contained in document EA 2/17 M:2020 shall apply.

5.1. Accreditation and/or Extension phases

In accordance with the general accreditation procedure outlined by the applicable Accreditation Regulations and in line with the decisions made by the relevant CSA for the Accreditation resolutions aimed at obtaining

subsequent Authorisations and Notifications from the Competent Authorities, the verification activities carried out by ACCREDIA are carried out in the following phases:

- Submission of Accreditation or Extension Applications by the CAB;
- Verification of the completeness of the Application(s) received and, following the successful outcome of such verification, issuance of the Quotation. The Quotation also indicates the intensity — understood as the frequency and number of man-days — of the Witness Assessments to be carried out, calculated on the basis of the Directives, Modules, Articles, Annexes and AVCP Systems, their criticality, and the homogeneous product families requested as the scope of accreditation);
- Acceptance of the Quotation by the CAB concerned, which formally initiates the conformity assessment activities;
- Carrying out of the Document Review for Accreditation or Extension;
- Execution of the Initial or Extension Assessment of the Accreditation at the CAB's offices. On such occasions, where the CABs are already Authorised and Notified, ACCREDIA assessment teams (GVI) carry out a full review of the files relating to certain CE-marking Certification Cases managed by the CABs, ensuring that the most critical ones are sampled (such as Modules, Articles, Annexes, AVCP Systems, and homogeneous product families - among those that may be available);
- Following a positive outcome of both assessment phases (Document Review and Office Assessment), the Accreditation or Extension file is submitted to the relevant CSA for the appropriate decision;
- Carrying out of selected Witness Assessments (where applicable to the Directives covered by the accreditation) with assessors of the Accredited and Notified Bodies, identified by applying the sampling criteria set out in Annex C of document EA 2/17 M:2020).

In view of the latter aspect — namely that the performance of selected Witness Assessments allows for the validation of the activities of Accredited and Notified Bodies on similar Modules within the same Directive — it is not necessary to carry out Witness Assessments for each individual Module/Article/Annex/AVCP System included in the scope of Accreditation. Such a decision cannot be made in advance; therefore, the issued Quotations indicate only the intensity — understood as the frequency and number of man-days — of the planned Witness Assessments, without specifying the individual Modules/Articles/Annexes/AVCP Systems.

It is also specified that Witnessing, in cases where Certification or Inspection or Validation Bodies request Accreditation for the purpose of subsequent initial Authorization for Notification or other forms of public authorization in regulated areas, ACCREDIA will carry out at least one Witness Assessment from those planned, during the first assessment activity carried out by the Body.

The witnessing (including the assessment of a Module B) shall be carried out within a maximum of 18 months after receiving accreditation/extension. If, during this period, the witnessing has not been carried out, then the accreditation for that conformity assessment activity will be withdrawn (first suspended, if necessary).

Once accreditation is withdrawn, the CAB may apply again; however, the option of being accredited with postponing of the witnessing (after the clients' requests have been received), will no longer be applicable. In such cases, the normal accreditation process must be followed, including the execution of the witnessing (obviously simulated) prior to the accreditation/extension decision.

5.2. Maintenance of Accreditation

During the accreditation cycle, through the performance of witness assessments and file reviews during office assessments, ACCREDIA must verify all the various conformity assessment procedures (Modules/Articles/Annexes/AVCP Systems) for the relevant regulations/directives included in the scope of accreditation.

The following factors must be considered when selecting the witness assessments:

- the number of technical staff involved in a specific conformity assessment activity;
- any changes in personnel;
- extensions to the scope;
- modifications to relevant equipment, testing methods, or the harmonised product standard (particularly in relation to the EN ISO/IEC 17025 accreditation) used for conformity assessment;
- demonstrated competence in the product type and related legislation;

as well as the sampling criteria for the modules defined in Annex C of document EA 2/17 M:2020.

If, at the end of the accreditation cycle, it is determined that it has not been possible to assess all the various conformity assessment procedures (Modules/Articles/Annexes/AVCP Systems) for the relevant regulations/directives, the situation must be assessed by the relevant CSA at the time of the renewal decision, which may take measures such as withdrawal, suspension, or reduction of accreditation.

In any case, it will not be possible to grant renewal for individual Modules/Articles/Annexes/AVCP System under the relevant Regulations/Directives if the Body has not demonstrated operational activity in those areas throughout the entire accreditation cycle, unless competence can be ensured/verified through the execution of witnesses or file reviews in alternative Modules/Articles/Annexes/AVCP Systems falling under the same Regulation/Directive, in accordance with the criteria set out in EA Document 2/17 M:2020, Tables 5 and 6 of Annex C, as reported below.

<table>
<tr><td colspan="3">Ref. Table 5 of document EA-2/17 M: 2020</td></tr>
<tr><td>Module to be included in the scope</td><td>Description of the module</td><td>Alternative module (s) to confirm competence</td></tr>
<tr><td>A1</td><td>Internal production control and supervised product testing</td><td rowspan="2">A1 or A2 or C1 or C2 or B or F or G</td></tr>
<tr><td>A2</td><td>Internal control of production and supervised product controls at random intervals</td></tr>
<tr><td>B</td><td>Type examination</td><td>B</td></tr>
<tr><td>C</td><td>Conformity with type based on internal production control</td><td>C or D or E or H or A1 or A2 or C1 or C2 or D1 or E1 or H1</td></tr>
</table>

Ref. Table 5 of document EA-2/17 M: 2020		
Module to be included in the scope	**Description of the module**	**Alternative module (s) to confirm competence**
C1	Conformity to type based on internal production control and supervised product testing	C1 or C2 or A1 or A2 or B or F or G
C2	Conformity with type based on internal production control and supervised product controls at random intervals	
D	Conformity to type based on quality assurance of the production process	D or D1 or H or H1 or E or E1
D1	Quality assurance of the production process	D1 or H1 or E1
E	Conformity to type based on product quality assurance	E or E1 or D or D1 or H or H1
E1	Quality Assurance of Final Product Inspection and Testing	E1 or D1 or H1
F	Conformity to type based on product verification	F or F1 or G
F1	Conformity based on product verification	F1 or G or B
G	Conformity based on unit verification	G or F1 or B
H	Conformity based on full quality assurance	H or H1
H1	Conformity based on full quality assurance and design control	H1

Ref. Table 6 of document EA-2/17 M: 2020	
AVCP-System to be included in the scope	**Alternative system-AVCP to confirm competence**
1+	1+
1	1 or 1+
2+	2+ or 1 or 1+

Ref. Table 6 of document EA-2/17 M: 2020	
AVCP-System to be included in the scope	**Alternative system-AVCP to confirm competence**
3	This is under ISO/IEC 17025 / testing, so witnessing or file review is included in the office assessment

In any case, the availability of the CAB's competence in the other Modules/Articles/AVCPs covered must be demonstrated.

In the case of conformity assessment procedures not aligned with Decision (EC) 768/2008, the following table shall be taken into consideration:

Directive	**Harmonized Standard**	**Description of the procedure**	**Alternative procedure to confirm competence**
2014/68/UE (PED)	ISO/IEC 17024	Approval of personnel performing non-destructive testing	Activities performed by the CAB under accreditation in areas not subject to Notification are regarded as similar.
	ISO/IEC 17024	Approval of permanent joining personnel performing	
	ISO/IEC 17020	Approval of permanent joining methods	

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