

GENERAL CERTIFICATION REGULATION
PRODUCTS, PROCESSES AND SERVICES
ACCORDING TO EN ISO/IEC 17065:2012

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1. THE IDENTITY OF THE CERTIFICATION BODY

VALIDX GROUP is a legal entity and is legally responsible for all certification activities performed under this Regulation. Its current legal identity, registered office and contact details are maintained in the applicable legal and corporate records.

Registered office: 4, Solonos street, 17673 Kallithea, Athens, Greece.

Operational addresses:

- Greek Office: 4, Solonos street, 17673 Kallithea, Athens, Greece
- Italian Office: Vimodrone, Via dell'Artigianato 18, Milano, Lombardia
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Telephone and email:

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2. CERTIFICATION SERVICES

VALIDX GROUP provides third-party certification of products, processes and services within its approved scope and in accordance with ISO/IEC 17065:2012, the applicable certification scheme, and the standards or other normative documents specified by that scheme.

This General Certification Regulation defines the rules governing certification and the respective rights and obligations of VALIDX GROUP, applicants and certified clients. Certification activities are limited to matters specifically related to the requested or granted scope of certification.

3. IMPARTIALITY, INDEPENDENCE AND CONFIDENTIALITY

VALIDX GROUP is responsible for the impartiality of its certification activities and does not permit commercial, financial or other pressures to compromise impartiality. Risks arising from its activities, relationships and personnel are identified on an ongoing basis, eliminated or minimized, and communicated to the mechanism for safeguarding impartiality. Top management is committed to impartiality.

All information obtained or created during certification is managed under legally enforceable confidentiality commitments. Except for information made public by the client, information agreed for disclosure, or information that VALIDX GROUP is legally or contractually authorized to disclose, client information is treated as confidential. The client is informed in advance of information intended for the public domain. Where disclosure is required by law, the client or person concerned is notified unless notification is prohibited by law. Information received from sources other than the client is also

confidential. The contents of the inspections, along with any other notes made during the inspection visit, are strictly confidential and are not disclosed to a third party without the written consent of the business/organization, unless required by the supervising authorities (ESYD etc.).

Personnel, committee members and external resources acting on behalf of VALIDX GROUP are bound by confidentiality and impartiality commitments. Conflicts of interest are declared before assignment and whenever circumstances change.

4. DEFINITIONS

a. Client: the organization or person responsible to VALIDX GROUP for ensuring that certification requirements, including product requirements, are fulfilled.
b. Certification requirement: a specified requirement, including product requirements, fulfilled by the client as a condition of establishing or maintaining certification.
c. Product requirement: a requirement that relates directly to a product, process or service and is specified in standards or other normative documents identified by the certification scheme.
d. Certification scheme: a conformity assessment system related to specified products, processes or services to which the same requirements, rules and procedures apply.
e. Scope of certification: identification of the product, process or service; the applicable certification scheme; and the standards or other normative documents against which conformity is certified.
f. Evaluation: the conformity assessment activities used to determine whether specified requirements are fulfilled, such as document review, sampling, testing, inspection or audit.
g. Review: verification of the suitability, adequacy and effectiveness of selection and evaluation activities and their results before a certification decision.
h. Certification decision: the decision to grant, maintain, extend, reduce, suspend, withdraw, terminate or refuse certification.
i. Impartiality: the presence of objectivity, including freedom from conflicts of interest and bias.
j. Consultancy: participation in designing, manufacturing, installing, maintaining or distributing a certified or to-be-certified product, or in designing, implementing, operating or maintaining a certified or to-be-certified process or service.
k. Complaint: an expression of dissatisfaction, other than an appeal, by any person or organization relating to VALIDX GROUP activities for which a response is expected.
l. Appeal: a request by a client for reconsideration of a certification decision.
m. Surveillance: systematic repetition of conformity assessment activities as a basis for maintaining the validity of certification.
n. Nonconformity: non-fulfilment of a certification requirement.
o. Product: throughout this Regulation, the term “product” may also be read as “process” or “service”, except where separate provisions apply.

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5. GENERAL REQUIREMENTS

Each certification activity shall be covered by an applicable certification scheme. Scheme requirements shall not contradict or exclude any requirement of ISO/IEC 17065. Relevant scheme-specific procedures and work instructions shall identify the applicable product requirements and evaluation methods.

The certification process includes, as applicable:

a. application and collection of required information;

b. completion of a legally enforceable certification agreement;

c. application review and planning of evaluation activities;

d. evaluation against the applicable product and scheme requirements;

e. independent review and certification decision;

f. issue of certification documentation, directory information, surveillance, changes and adverse certification actions, as applicable.

Certification documentation is issued only after the decision to grant or extend certification has been made, all certification requirements have been fulfilled, and the certification agreement has been completed or signed. VALIDX GROUP may additionally apply the agreed financial conditions, provided these do not compromise impartiality or constitute undue conditions.

6. ASSESSMENT AND CERTIFICATION PROCESS

General

VALIDX GROUP operates one or more certification schemes covering its certification activities. Products are evaluated against the requirements contained in the standards and other normative documents specified by the applicable scheme. Any explanations concerning application of those documents are formulated by relevant, impartial and technically competent people or committees and are made available upon request.

Application

VALIDX GROUP uses an application process to obtain all information necessary to complete certification under the relevant scheme. Collection of application information may be combined with, or separate from, the certification agreement.

Application information includes, as applicable:

a. the product, process or service to be certified;
b. the standards and other normative documents for which certification is sought;

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c. the client identity, locations, relevant operations and legal obligations;
d. information on the client's activities and human and technical resources relevant to the requested scope;
e. outsourced client processes that may affect conformity, including relevant production entities and contractual controls needed for effective surveillance;
f. other information required for initial evaluation and surveillance, including production locations and contact personnel.

Applications for extension of certification scope are processed using the applicable requirements for application, review, evaluation and decision.

Application Review

VALIDX GROUP reviews each application to ensure that:

a) customer and product information is sufficient to carry out the certification process
b) resolve any known understanding dispute between the certification body and the customer, including agreement on standards or other regulatory documents;
c) the requested scope of certification is defined;
d) the means to perform all evaluation activities are available;
e) VALIDX GROUP has the competence and capability to perform the certification activity.

Where a request concerns a product type, normative document or scheme with which VALIDX GROUP has no prior experience, competence and capability are confirmed and the justification for undertaking the certification is recorded.

VALIDX GROUP declines certification work when it lacks the required competence or capability.

Where existing certifications are relied upon to omit activities, those certifications and the justification for omission are recorded. The justification is provided to the client upon request.

Evaluation

VALIDX GROUP issues an implementation plan for evaluation activities (Evaluation Program) which allows for the effective management of the necessary arrangements. The plan can be either general for all evaluation activities (including evaluation of the management system where necessary) or a specific evaluation implementation plan for each individual evaluation activity or a combination of both). The Evaluation Program includes all the necessary information for the successful implementation of the evaluation

Competent personnel are assigned to internal evaluation tasks. Outsourced evaluation activities are controlled in accordance with the approved provider arrangements and remain the responsibility of VALIDX GROUP.

All necessary information and documentation are made available. Evaluation is performed in accordance with the plan against the requirements covered by the certification scope and the applicable scheme.

Holding an inaugural meeting

At the beginning of each inspection, an introductory session is held with the client's Management and, where appropriate, with those responsible for the activities or processes inspected. The purpose of the opening or introductory session, which is usually conducted by the head of the inspection team, is to give a brief explanation to the client of how the inspection activities will be carried out.

During the inspection, the inspection team periodically assesses the progress of the inspection and exchanges necessary information, which has been collected in the meantime. The audit team leader may assign new tasks or new roles, if necessary, to the members of the inspection team and periodically report on the progress of the inspection and potential entanglements to the client.

Obtaining and confirming information

During the inspection, information relevant to the objectives of the inspection, scope and criteria (including information related to interactions between functions, activities and processes) is collected by appropriate sampling on a case-by-case basis and verified for objective evidence.

Identification and recording of inspection findings

Audit findings summarizing conformities and detailed nonconformities are identified, classified and recorded to support an informed certification decision given or maintained. VALIDX GROUP issues Nonconformities and observations regarding deviations identified during inspections.

Preparation of inspection conclusions

Under the responsibility of the lead inspector, upon completion of the inspection and before the closing meeting, the inspection team prepares the conclusions of the inspection.

Holding of a closing meeting

Before the end of the inspection, a final meeting is held with the customer's management and, where appropriate, with those responsible for the inspected functions or processes, where the presence of all involved is recorded. The purpose of the closing session, which is conducted by the head of the inspection team, is to present the conclusions of the inspection including the recommendation regarding certification

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to the customer. Any identified nonconformities are presented so that the course of action for them is understood and the timetable for corrective actions agreed.

Inspection report

VALIDX GROUP provides a written report to the customer for each inspection it conducts. For the cases of certification of products, systems or processes, the appropriate forms are used, which refer to the special Regulations. The inspection report is communicated to the customer on the same day or on another agreed date but remains the property of VALIDX GROUP.
Audit reports are kept in the company's records. Observations or data obtained during checks shall be recorded in a timely manner to avoid loss of relevant information. In addition to non-compliance, the auditor is obliged to report problems that he/she finds before the beginning of the audit, and which may affect the smooth conduct of the audit. These are recorded and the customer is informed.

Root Cause Analysis of non-conformities

VALIDX GROUP requires its customers to analyze the causes and describe the specific corrections and corrective actions they will undertake or plan to take in order to eliminate nonconformities within a specific time frame. The client is obliged to record in the form accompanying the inspection report "Non-Conformities", both the details of the investigation of the root causes of the identified findings and the plan of corrections and corrective actions it intends to implement to remove and eliminate the problem.
In addition, the timetable for the implementation of the response plan is recorded in compliance with the respective time constraints established by VALIDX GROUP.

Effectiveness of corrections and corrective actions

VALIDX GROUP confirms the effectiveness of any correction or corrective action taken. Evidence obtained to support the resolution of nonconformities is recorded and archived. The customer is informed of the outcome of the review and confirmation.

Review

At least one competent person reviews all information and results relating to the evaluation. The reviewer shall not have been involved in the evaluation. Recommendations arising from review are documented unless review and decision are performed concurrently by the same eligible person or group.

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Certification Decision

VALIDX GROUP retains responsibility and authority for all certification decisions. At least one competent person makes the decision based on the evaluation, its review and other relevant information. Decision-makers shall not have been involved in the evaluation and shall meet the employment or contractual-control requirements of ISO 17065 Clauses 7.6.3–7.6.5. A lead evaluator shall not make the certification decision for work in which that person participated. When certification is refused, the client is notified of the decision and the reasons.

Certification documentation

Formal certification documentation issued by VALIDX GROUP clearly identifies:

a. the name and address of VALIDX GROUP;
b. the date certification is granted, which shall not precede completion of the certification decision;
c. the client's name and address;
d. the scope of certification;
e. the term or expiry date, where applicable;
f. any other information required by the certification scheme.

Certification documentation includes the signature or other defined authorization of the person assigned responsibility by VALIDX GROUP.

7. CERTIFICATION DIRECTORY, SURVEILLANCE AND SCOPE EXTENSION

VALIDX GROUP maintains information on certified products, processes and services that identifies the certified subject, the standards or other normative documents, and the client. At minimum, information on the validity of a specified certification is provided upon request. Publication is governed by the applicable scheme.

Where surveillance is required by the scheme or by continued use of a certification mark, VALIDX GROUP initiates surveillance in accordance with the scheme. Any evaluation, review or certification decision used in surveillance fulfils the applicable requirements of ISO 17065 clauses 7.4, 7.5, 7.6. and 7.9.

Where a certification mark continues to be used on a product, its packaging or accompanying information, periodic surveillance of marked products is performed. For processes and services, periodic surveillance activities are performed to confirm continued fulfilment of requirements.

An extension of scope is treated as a change to certification and is subject to application review and any evaluation, review, decision and revised documentation required by the scheme and the nature of the extension.

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The extent of evaluation for additional product variants is determined and justified under the applicable scheme; activities are not omitted solely because production occurs at an existing location.

For additional locations, VALIDX GROUP determines and performs the activities necessary to obtain sufficient objective evidence for the extended scope.

Extension activities may be coordinated with scheduled surveillance where the scheme permits, and all applicable requirements are fulfilled.

8. TERMINATION, REDUCTION, SUSPENSION OR WITHDRAWAL OF CERTIFICATION

When nonconformity with certification requirements is substantiated, whether through surveillance or otherwise, VALIDX GROUP considers and decides the appropriate action.

- Appropriate action may include continuation under specified conditions, including increased surveillance;
- reduction of scope to remove nonconforming product variants, processes, services or locations;
- suspension pending remedial action by the client;
- or withdrawal of certification.

Where an action includes evaluation, review or a certification decision, the applicable requirements of ISO 17065 Clauses 7.4, 7.5 or 7.6 are fulfilled.

Termination, suspension, withdrawal or reduction are implemented in accordance with the scheme and contract. Certification documents, public information and authorizations to use marks are updated so that certification status and scope are represented accurately.

If certification is suspended, competent personnel define and communicate the actions required to end the suspension and restore certification, together with any other scheme requirements.

Any evaluation, review or decision required to resolve suspension is performed under the applicable certification-process requirements.

After reinstatement, certification documents, public information and authorizations are updated to show the restored status and any reduced scope accurately.

Additional contractual grounds for action may include misuse of certification, failure to cooperate, failure to implement required changes, or failure to meet agreed financial obligations, provided the action is consistent with the scheme, agreement and the requirements above.

VALIDX GROUP notifies the client in writing of the action, its effective date, the reasons, applicable conditions and available appeal process.

Audited document Do not reproduce without permission

During suspension, the client shall cease claims and use of marks as specified by the scheme and VALIDX GROUP instructions.

The client shall complete the communicated remedial actions within the established time frame and provide objective evidence.

Continued unauthorized use of certification claims or marks is addressed through suitable action, which may include corrective action, withdrawal, publication of the transgression or legal action.

Where certification is withdrawn or terminated, the client shall return or discontinue use of certification documents and marks as required by the scheme and agreement.

Where product-related action is necessary, VALIDX GROUP determines and communicates appropriate measures under the certification scheme and applicable legal requirements.

VALIDX GROUP updates the certification directory and public information without undue delay.

For the fields that fall within the scope of application of M.D. F.01.2/56790/DPP 1828 (Government Gazette 1897B/27-6-2016) and UNHCR oik. 74124/ΔΤΒΝ 1431 Φ.Ε.Κ.2278/Β' 22.7.2016, VALIDX GROUP informs the Notifying Authority as well as the other Notified Bodies operating in the same field of Union harmonization legislation about the temporarily or permanently revoked certificates. In case of permanent revocation, the respective products or services shall be deleted from the List of Certified Products, while in cases of temporary revocation, VALIDX GROUP makes a relevant indication in the Catalogue and notifies the competent bodies.

9. RIGHTS AND OBLIGATIONS OF THE CLIENT

The client shall make certification claims only within the granted scope, shall not bring VALIDX GROUP into disrepute, and shall not make misleading or unauthorized statements about certification.

The client shall:

a. Provides all information and cooperation necessary to complete certification;
b. continually fulfils certification requirements and implements changes communicated by VALIDX GROUP;
c. Makes arrangements for evaluation and surveillance, including access to documents, records, equipment, locations, areas, personnel and relevant subcontractors; It is also obliged to allow free access to ESYD inspectors when requested.
d. To inform VALIDX GROUP of any change in the data of the technical file submitted to it, as well as in its production process, and/or in the quality system applied, that have an impact on the certification granted. This notification should be submitted in writing within twenty (20) days from the implementation of the change. Otherwise, VALIDX GROUP may take appropriate measures (such as withdrawal of the certificate, notification of the supervisory authorities, judicial measures, etc.).

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e. If VALIDX GROUP decides that the changes made require further checks, the customer shall be informed in writing that he should not place on the market certified products affected by these changes, until he is informed accordingly by VALIDX GROUP;
f. To respect the decisions of VALIDX GROUP concerning the certification of its product and especially those concerning the withdrawal, suspension or expiration of the certificate. In such cases, it must stop advertising or making any reference to the certification and return the certificate issued to VALIDX GROUP as soon as possible.
g. Use licenses, certificates, marks and other certification indicators only as authorized;
h. Use and display only the certification and / or copies thereof of the specific product and / or the scope of certification and the standards with which it was certified.
i. Maintains records of complaints relating to compliance with certification requirements and make them available to VALIDX GROUP on request;
j. Takes the necessary actions in case of complaints from its customers when defects of its certified products are found, affecting their compliance with the requirements of certification and keeping records of the above actions. Keep a record of all complaints regarding compliance with certification requirements and make records available to the Certification Body upon request. The client should also examine the merits of complaints, take appropriate action regarding complaints and deviations of products that affect compliance with certification requirements, investigate the causes of any non-conformities and take appropriate corrective action, which it should document.
k. To fulfill its financial obligations to VALIDX GROUP for the certification of its product and the expenses of the inspectors, in accordance with the pricing policy of the Agency.
l. The client takes all necessary actions to:
    i. Carrying out assessment and surveillance (if required), including provision for reviewing documentation and records, as well as access to relevant equipment, location(s), area(s), personnel and subcontractors of the client
    ii. Participation of observers, if required.
m. Can object to the certification only in terms of the scope of certification.
n. In case it provides copies of the certification documents to others, these documents should be reproduced in their entirety or as specified by the Certification Scheme.
o. When reporting the customer on the certification of its products in media such as websites or brochures, it should comply with the requirements of the Certification Body or as specified in the certification scheme and comply with the requirements imposed by the certification scheme regarding the use of conformity marks; as well as with information about the product.
p. If the certification is valid for series production, the certified product still meets the product requirements.
q. After any suspension, withdrawal or termination of certification, the customer discontinues the use of all advertising material containing any reference to certification and acts as required by this certification scheme (e.g. discontinuation of the product or its withdrawal from the market, return

or renewal of the validity of certification documents, etc.) while taking any other required measure regarding the certification of these products as notified by VALIDX GROUP

The certificates issued by VALIDX GROUP do not relieve the customer of his responsibilities under the applicable Legislation governing the processes related to the offered products or from his contractual obligations towards his customers.

VALIDX GROUP bears no responsibility for the disposal of defective products, by a certified customer, to third parties nor is it liable for damage caused by the above.

The customer bears full responsibility for any damage that may arise from the placing or use of his certified products on the market.

10. COMPLAINTS AND APPEALS

Any person or organization may submit a complaint concerning VALIDX GROUP certification activities. A client may appeal a certification decision. Submissions may be made using the form published on the website by VALIDX GROUP.

Receipt of a formal complaint or appeal is acknowledged. VALIDX GROUP confirms whether the matter relates to certification activities for which it is responsible and, where it does, addresses it.

VALIDX GROUP maintains a documented process to receive, evaluate and decide complaints and appeals, and records and tracks each matter and the actions taken to resolve it.

In case of non-granting of the Certification, the interested party may submit a reasoned objection against the results of the inspection to the Agency. The deadline for submitting the objection is set at five (5) working days from the announcement of the Agency's decision.

The customer may appeal to VALIDX GROUP within two months from the notification to him of the relevant decision or from the date on which he is proven to have become aware.

In any case of objection to the Certification decisions, the Impartiality Committee is activated. The Committee's operating procedure for handling an appeal is as follows:

- The Impartiality Committee is established and examines the objection within 30 days of its submission.
- The Commission has full authority to invite any person (client, witness, staff Agency, external consultants, experts) it deems appropriate to contribute to the complaint. Each invitee is informed about the topic and his/her place of attendance at least 7 calendar days before the date of the meeting.
- The objector has the right to object to any member of the Impartiality Committee if he provides relevant documentation for the reasons he does not wish to participate in the Committee, no later

than 3 calendar days after sending a relevant information leaflet to him. Until the examination of the objection by the Commission, the previous relevant decision will be in force. The appellant receives formal notice of the appeal outcome and closure.

- If the Impartiality Committee decides on the objections with a positive outcome as far as the interested party is concerned, then he/she may participate again in the Inspection process without the re-charge. If the outcome of the appeal concerns incorrect implementation of the obligations of the Inspection or any irregularities, the Agency ensures that the necessary corrective actions are taken.
- Any decision of the Impartiality Committee is final and cannot be revoked/amended by another body. The Commission's decision shall be communicated to any interested party within 2 working days of its adoption. Copies of Commission decisions shall be issued to any interested party.

11. FINANCIAL TERMS

The customer will have to pay the total cost agreed with the Entity in the signed contract, before sending the certificate to the customer. Non-compliance with the financial terms by the customer is a reason for termination of cooperation and revocation or non-dispatch of the issued certificate.

12. AMENDMENTS TO THE STANDARD CONDITIONS FOR GRANTING CERTIFICATES

VALIDX GROUP retains certification when it is demonstrated that the customer continues to meet the requirements of the relevant standard or certification scheme.

Suspension, revocation or reduction of the scope of certification

VALIDX GROUP may suspend, revoke or reduce the scope of its customer certification. When a documented non-compliance with certification requirements is detected (as a result of surveillance activities or otherwise), the Technical IMF becomes aware of and decides on appropriate actions, which may be one of the following:

(a) continuation of certification under the conditions laid down by the certification scheme;

(b) reduction of the scope of certification to exclude products/processes/services related to non-compliance

(c) suspension of certification until corrective actions are taken by the customer

(d) withdrawal of certification

If the certification is suspended, VALIDX GROUP notifies the customer with the following:

- Actions required to lift the suspension of certification
- Any other necessary actions.

VALIDX GROUP may assign the implementation of these actions to executives with appropriate competence by keeping a record of this assignment.

If certification is restored after suspension, VALIDX GROUP updates the information in certification documents and publications about certification and reinstates the authorization to use certification marks and claims to demonstrate the continued certification of the products/processes/services involved.

If a decision to reduce the scope of certification is taken as a condition of restoration of certification, VALIDX GROUP updates the information in certification documents and publications on certification and reinstates the authorization to use certification marks and claims to ensure that the reduced scope is properly reflected in the certification documents and publications of the products/processes/services involved.

13. OBLIGATIONS OF VALIDX GROUP

VALIDX GROUP assumes responsibility towards the customer for the faithful observance of the articles of this GDPR and the decisions taken within it.

Certification activities are performed by competent personnel. Evaluation, review and decision responsibilities are assigned so that the required independence is maintained.

When a certification scheme introduces new or revised requirements that affect clients, VALIDX GROUP shall notify all affected clients in writing, specifying the changes, applicable implementation deadlines and any evidence or activities required to demonstrate conformity. VALIDX GROUP shall verify implementation through review of submitted evidence, and where necessary or required by the scheme, additional evaluation activities. The results shall be recorded, and VALIDX GROUP shall take the actions required by the scheme, including appropriate action where a client fails to implement the changes within the specified timeframe.

VALIDX GROUP shall not be liable in the event that claims for liability are made for damage caused by defective products or services of the certified customer. In cases where such claims arise, the customer is obliged to inform VALIDX GROUP immediately and in writing.

VALIDX GROUP has an obligation to inform the customer, as well as the relevant National Control Bodies, when he receives complaints about the quality of his products. In case claims are raised against the Certification Body by any third party, private or public, for an event for which the Body is not responsible, the Customer is obliged to release the Control Body from any third-party claim.

In any case, the Certification Body is entitled to recourse claim from the Customer to pay him any compensation he may have paid to third parties for an event for which he is not responsible and is not related to the audit and certification process.

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AMENDMENTS

Edition	Chapter	Amendments Description	Drafted by	Approved by	Date
v.2 -> **v.3**	Overall	Format Change and Group Structure Information Showcasing the relationship with the new entity VALIDX and the IMS Implementation	Athanasios Arvanitis (Quality Manager)	Angelos Koulourids Stergios Zarifidis Sara Pellegrino	13/05/2025
v.3 -> **v.4**	Overall	Alignment with ISO/IEC 17065:2012; correction of terminology, certification-process controls, appeals, surveillance and change requirements.	Ioannis Garinis (IMS Manager)	Angelos Koulourids Stergios Zarifidis	07/09/2026
v.4 -> **v.5**	§13	Added VALIDX GROUP's obligations to communicate changes in certification scheme requirements, verify client implementation and take the required actions in accordance with ISO/IEC 17065	Ioannis Garinis (IMS Manager)	Angelos Koulourids Stergios Zarifidis	01/11/2026

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