1. IDENTIFICATION OF THE CERTIFICATION BODY

Company name: VIACERT Certificadora Ltda.

CNPJ (Brazilian company registry): 60.739.272/0001-30

Address: Rua Alice Além Saadi, 855 - Sala 1504 - CEP 14096-570 - Ribeirão Preto/SP - Brazil

Legal Representatives: Rogerio Augusto de Oliveira / Vitor Hugo Garcia

Technical Representative: Rogerio Augusto de Oliveira — Technical Director

Contact: contato@viacert.com.br

2. PURPOSE AND SCOPE

The purpose of this guideline is to inform the external professionals who perform, or intend to perform, evaluation activities conducted by VIACERT Certificadora Ltda., as External Auditor or as Technical Expert, about the qualification requirements, the rules applicable to their work, the commitments they undertake and the way in which their performance is monitored.

It applies to the certification scheme for Non-Surgical Procedure Gloves and Surgical Gloves, in accordance with ECP 7.1-01, and presents, in guidance language, the criteria established in PRO 6.1-02 – Procedure for the Qualification of External Auditors and Technical Experts.

This guideline is informative. In the event of any divergence, the TCP – Professional Commitment Term for Certification Activities signed by the professional and the internal procedures of VIACERT shall prevail.

3. DEFINITIONS

For the purposes of this guideline, the following definitions apply:

- **External Auditor:** external professional, under direct contract with VIACERT, qualified and authorized to conduct audits of the Quality Management System and of the manufacturing process of the manufacturer, as well as audits of the applicant.
- **Technical Expert:** professional who provides specific knowledge or expertise to the audit team, in accordance with clause 3.16 of ABNT NBR ISO 19011:2018, not acting as an auditor and not issuing conformity findings independently.
- **Qualification:** formal recognition, recorded in the PQR1, that the professional meets the education, training, technical knowledge and experience criteria established by VIACERT.
- **Authorization:** formal approval for the qualified professional to be assigned to evaluation activities, subject to the signature of the TCP.
- **PQR1:** Qualification and Competence Report for External Auditor and Technical Expert, in which the professional declares his or her education, training, knowledge of the technical standards and experience, and in which VIACERT records the result of the assessment and the authorization granted.
- **TCP:** Professional Commitment Term for Certification Activities, by which the professional undertakes the commitments of confidentiality, impartiality, ethics, professional conduct and responsibility.
- **RVI:** Impartiality and Conflict of Interest Verification Record, a block forming part of the audit report, in which the professional declares his or her impartiality before the start of each activity.
- **RMA:** Performance Monitoring Report for External Auditor and Technical Expert, issued by VIACERT upon the completion of each activity.

4. QUALIFICATION

4.1 Required documents

For the qualification analysis, the professional shall submit to VIACERT:

- PQR1 fully completed, dated and identified;
- updated professional curriculum vitae;
- diploma or certificate of completion of the declared education;
- certificate of the ISO 9001 Lead Auditor Course, mandatory for the External Auditor;
- certificate of the ISO 9001:2015 Requirements Interpretation Course, when applicable;
- certificates or supporting documents of the additional training declared;
- TCP dated and signed.

Where the Lead Auditor Course was completed on the basis of ISO 9001:2000 or ISO 9001:2008, the certificate of the ISO 9001:2015 Requirements Interpretation Course shall be submitted, and a new Lead Auditor certification is not required. For the Technical Expert, the PQR1 fields relating to the Lead Auditor Course are completed as not applicable.

Documents are accepted in Portuguese, English or Spanish. Documents issued in other languages shall be accompanied by a simple translation into Portuguese or English, under the responsibility of the professional. The information declared is corroborated by the curriculum vitae, and audit reports issued for other bodies are not requested, in view of the confidentiality obligations to which the professional is subject.

4.2 Competence criteria – External Auditor

- **Education:** completed higher education, evidenced by a diploma or certificate of completion.
- **Training:** ISO 9001 Lead Auditor Course and, when applicable, ISO 9001:2015 Requirements Interpretation Course.
- **Technical and normative knowledge:** ABNT NBR ISO 9001:2015 and ABNT NBR ISO 19011:2018, in addition to the knowledge applicable to audits of the Quality Management System and of the manufacturing process of medical gloves.
- **Practical experience:** at least 3 (three) Quality Management System audits in manufacturing units, carried out within the last 10 (ten) years, of which at least 1 (one) in the manufacturing of medical gloves, which may have been performed as lead auditor, auditor or auditor in training.

The knowledge of the product technical standards declared in the PQR1 is informative for the External Auditor: it does not prevent the qualification or the authorization and is used by VIACERT to determine the need for a prior technical alignment before the assignment.

4.3 Competence criteria – Technical Expert

- **Education:** completed technical or higher education, evidenced by a diploma or certificate of completion.
- **Training:** no specific training is required, and the Lead Auditor Course is not a requirement for this role.
- **Technical and normative knowledge:** technical standards applicable to medical gloves (ISO and ASTM series) and knowledge of the manufacturing process, of the quality controls and of the applicable tests. Knowledge of ABNT NBR ISO 9001:2015 is desirable but does not constitute a requirement.
- **Practical experience:** at least 2 (two) years in activities related to medical gloves, the sum of non-concurrent periods being accepted, evidenced by participation in external audits, direct work in glove manufacturing companies, provision of technical consultancy or provision of testing laboratory services.

For the Technical Expert, the declaration of knowledge of the product technical standards forms part of the competence assessment and is considered together with the evidenced practical experience.

4.4 Assessment and authorization

The technical assessment is carried out by the Technical Director, who records in the PQR1, for each role, the result as Qualified, Not Qualified or Not Assessed, together with the justification for the decision. Where the

result is Not Qualified, the professional is formally informed of the requirements not met and may submit a new request after complementing them.

The authorization is granted after the Qualified result and the signature of the TCP, and specifies the authorized role or roles, the certification scheme, the activities for which the professional is authorized and any restrictions, with the date of the authorization and its validity being recorded.

4.5 Validity and maintenance of the qualification

- the qualification is valid for 5 (five) years, counted from the date of the authorization;
- every 2 (two) years, the professional shall send the updated curriculum vitae and confirm that there has been no relevant change in his or her personal data and in the declared affiliations;
- the professional who remains without activity for a period longer than 24 (twenty-four) months has his or her qualification reassessed before a new assignment;
- the reassessment may be brought forward where there is an unsatisfactory performance assessment, a substantiated complaint or a relevant change in the normative requirements applicable to the scheme.

5. ASSIGNMENT TO THE ACTIVITIES

The assignment to each activity is formally communicated by VIACERT and observes the current authorization of the professional. The assignment communication informs the certification process, the manufacturer or applicant, the scope, the dates and the composition of the team.

In the planning of the evaluation, VIACERT provides the professional with the product standard applicable to the scope, the test plan, the criteria of the certification scheme and the forms to be used. Where relevant, a prior technical alignment on the applicable product standard and test plan is conducted and recorded in the assignment communication.

The composition of the team observes the following rules:

- audit of the applicant: carried out by the External Auditor, without the participation of a Technical Expert;
- sample collection and sealing: carried out by a professional authorized for the activity, without the participation of a Technical Expert;
- audit of the factory and of the manufacturing process: requires an External Auditor and a Technical Expert, and a single professional may be assigned where he or she holds both qualifications.

VIACERT does not assign auditors in training to perform evaluation activities.

6. IMPARTIALITY, CONFIDENTIALITY AND CONDUCT

By signing the TCP, the professional undertakes permanent commitments, among which the following are highlighted:

- not to provide technical consultancy, advisory services or training to clients with certification processes active at VIACERT, where related to the product, to the manufacturing process or to the management system subject to the evaluation;
- to decline participation in activities related to clients with whom he or she has had a personal, professional, commercial or corporate relationship in the last 2 (two) years;
- to declare in advance any past or present association, of his or her own or of the organization to which he or she is linked, with the parties involved in the process;
- to immediately inform VIACERT of any actual, potential or perceived situation that may compromise his or her impartiality;
- to maintain permanent confidentiality regarding all information obtained as a result of the activities performed.

Before the start of each activity, the professional declares his or her impartiality in the RVI, a block forming part of the audit report, confirming that there are no exceptions to report or describing in detail the situations identified. At the end of the activity, he or she confirms that the declarations remain valid.

Any situation identified is analysed and addressed by VIACERT before the start or the continuation of the activity, and may result in the adoption of control measures, in the replacement of the professional or in his or her impediment to take part in the process.

7. PERFORMANCE OF THE ACTIVITIES AND EXPECTATIONS REGARDING THE WORK DELIVERED

The activities shall be performed in accordance with the procedures, the criteria and the forms of VIACERT, and the reports shall be delivered complete and within the agreed deadlines. The items below describe what VIACERT expects from the work delivered and correspond to the criteria used in the performance monitoring:

- Coverage: to address all the requirements set out in the audit plan, in the applicable standard and in the criteria of the certification scheme, without omitting requirements or areas of the scope.
- Traceability: to clearly identify the objective evidence examined, including documents, records, samples, interviews and observations of the manufacturing process.
- Drafting: to write with clarity, objectivity and technical accuracy, without ambiguity and in language that allows the analysis by third parties who did not take part in the activity.
- Correlation: to link each finding to the corresponding normative or regulatory requirement.
- Substantiation: to appropriately describe and classify the nonconformities and the observations, always on the basis of evidence.
- Sufficiency: to deliver information that allows the analysis and the certification decision to be conducted without the need for relevant additional clarification.
- Formality and deadlines: to complete the applicable forms fully and correctly, including the RVI, and to meet the execution and delivery deadlines.
- Conduct: to act with impartiality and professional demeanour, maintaining appropriate communication with the client during the activity.

8. PERFORMANCE MONITORING

The performance of the professional is assessed upon the completion of each activity, on the basis of the documents delivered by him or her, and recorded in the RMA. Each of the criteria of item 7 is classified as Poor, Below Expectations, Satisfactory, Excellent or Not applicable, and a final assessment of the activity is issued as Satisfactory, Satisfactory with recommendations or Unsatisfactory.

The RMA is filed in the dossier of the professional. There is no formal communication of the result of each activity; the improvement points identified are shared whenever VIACERT considers it relevant, in particular where the report is returned for completion or correction.

Where unsatisfactory performance is identified, VIACERT may adopt, individually or cumulatively, the following measures:

- return of the report for completion or correction, within a defined deadline;
- technical alignment on the applicable requirements, criteria and forms;
- restriction of the scope of the authorization;
- temporary suspension or cancellation of the authorization, in accordance with Section 6 of the TCP;
- bringing forward the reassessment of the qualification.

9. COMMUNICATION CHANNELS AND FINAL PROVISIONS

Communications relating to the qualification, to the assignment and to the performance of the activities may be made in Portuguese, English or Spanish, through the official channels of VIACERT:

- Technical Director: Rogerio Augusto de Oliveira
- E-mail: rogerio@viacert.com.br
- Telephone/WhatsApp: +55 (16) 98144-4444
- Mail: Rua Alice Além Saadi, 855 - Sala 1504 - CEP 14096-570 - Ribeirão Preto/SP - Brazil

This guideline is available to the external professionals on the institutional website of VIACERT, where its most up-to-date version may be consulted: www.viacert.com.br

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This document is issued in Portuguese and in English, with the same identification, revision and effective and expiry dates. In the event of any divergence in interpretation between the versions, the Portuguese version shall prevail.

VIACERT reserves the right to update this guideline whenever there are changes in its internal procedures, normative or regulatory updates or improvements in the qualification and assignment processes, and it is incumbent upon the professional to consult the current version before each activity.

In case of doubts regarding the content of this guideline, the professional may contact the Technical Management of VIACERT through the channels indicated.

10. REVISION HISTORY

REVISION	Description of the change	Effective date (dd/mm/yyyy)	Expiry date (dd/mm/yyyy)
00	Issue. Document prepared in order to provide the External Auditors and the Technical Experts, in guidance language, with the qualification requirements, the rules applicable to their work, the commitments undertaken in the TCP and the criteria used in the performance monitoring, established in PRO 6.1-02 - Procedure for the Qualification of External Auditors and Technical Experts.	05/01/2026	04/01/2028

11. PREPARATION, CRITICAL REVIEW AND APPROVAL

	DATE	RESPONSIBLE ROLE	NAME
Preparation	05/01/2026	Technical Director	Rogerio Augusto de Oliveira
Critical Review Approval	05/01/2026	Commercial Director	Vitor Hugo Garcia

This document was prepared, reviewed and approved in accordance with the applicable requirements of the Management System of VIACERT, and is correlated with the respective Normative Verification Lists (LVN) of the organization, as follows:

- LVN 8.3-01 – Normative Verification List – NBR ISO/IEC 17065:2013 – Revision: 00
- LVN 8.3-02 – Normative Verification List – Portaria MTP 672:2021 – Annex D – Revision: 00