
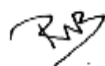


	<b>Dutch Institute of Quality Certifications</b>	<b>Document no.</b>	<b>D-MMS-S-0016</b>
		<b>Rev. No</b>	<b>02</b>
	Suspension, Withdrawal or Reduction in scope of Certification	<b>Date</b>	<b>07-01-2024</b>

**Dutch Institute of Quality Certifications** (hereinafter referred as *DIQC B.V.*)

**“Suspension, Withdrawal or Reduction in scope of Certification”**

*(Clause 9.6.5 of ISO/IEC 17021-1: 2015)*

Process Description	Name	Signature
Prepared by	Jaya Yadav	
Reviewed & Approved by	Ranjit Rajemahadik	

**Revision History**

Sr. No.	REVISION NO.	CRN NO.	EFFECTIVE DATE	REASON FOR CHANGE	AUTHORIZED BY
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**Dutch Institute of Quality  
Certifications**

Suspension, Withdrawal or  
Reduction in  
scope of Certification

**Document no.**

**D-MMS-S-  
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**Date**

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1	00	Not Applicable	15-07-2021	Initial Release	Document Controller
2	01	CRN/23/01	18-04-2023	- Periodic review of procedure is carried out and revised section 3 for references as per current organization chart.	Document Controller
3	02	CRN/23/04	07/01/2024	Updated the procedure for providing information to the Regulatory Authority and ensure that relevant personnel are aware of their responsibilities in fulfilling this requirement.	Document Controller



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## 1. Purpose

To document a procedure for conducting activities of ‘Suspension, Withdrawal or Reduction in scope of Certification’.

## 2. Scope

This procedure is applicable for Medical Device Management System Certification.

## 3. Responsibility

- 3.1 Director Operations
- 3.2 Programme Manager

## 4. Definitions/Abbreviations

Refer ‘D-MMS-G-0001 Definitions’ for any further definitions.

## 5. References

- 5.1 ISO/IEC 17021-1: 2015 Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements

## 6. Procedure


### 6.1 Suspension:

6.1.1 Certification status of a certified client leads to suspension, in cases when;

- a) The client's certified management system has persistently or seriously failed to meet certification requirements, including requirements for the effectiveness of the management system
  - A situation, where in the corrective action plan is not evidenced during a surveillance audit for the minor non conformities raised during previous surveillance audit. An additional audit is recommended at this stage and the client is advised to effectively close all the non-conformities within the defined time period. A failure to close the non-conformities during this stipulated period leads to a situation termed as persistent failure.

	<b>Dutch Institute of Quality Certifications</b>	<b>Document no.</b>	<b>D-MMS-S- 0016</b>
		<b>Rev. No</b>	<b>02</b>
	Suspension, Withdrawal or Reduction in scope of Certification	<b>Date</b>	<b>07-01-2024</b>

- A situation, where in the corrective action plan is not evidenced during an additional audit for major non conformities raised during the surveillance audit in defined time period is termed as a serious failure.
  - An improper use of DIQC certification mark and/or Accreditation Mark (as permissible) is evidenced (e.g. certification mark and/or Accreditation Mark (as permissible) is applied on the product or the certified client has no. of companies and the certification mark and/or Accreditation Mark (as permissible) is used for all the group companies without getting certification for all the group companies) and reported to the certified client but no actions taken by the client against the reported irregularities.
- b) The certified client does not allow surveillance audits to be conducted at the required frequencies even after sending two written notifications at a gap of 15 days between each respective notification. The first surveillance audit must be conducted within the defined time period
- c) The certified client has voluntarily requested a suspension.
- d) The client fails to comply with the due settlement of financial obligation of DIQC, even after sending two written notifications at a gap of 15 days between each respective notification.
- 6.1.2 Certification is suspended for a period not exceeding three consecutive months under the authority of Operations Head.
- 6.1.3 Official Suspension Letter is sent to via email. This letter instructs the client to discontinue use of all advertising matter that contains any certification claim/matter, till the suspension is lifted.
- 6.1.4 Under suspension, the client's management system certification is temporarily invalid. DIQC B.V. ensures enforceable arrangements through legally enforceable certification agreement with its clients to ensure that in case of suspension the client refrains from further promotion of its certification status. DIQC makes the suspended status of the certification publicly accessible and takes other suitable measures, if it deems appropriate.
- 6.1.5 Removal of suspension is subject to an investigation/review by DIQC B.V. To remove the suspension, the certified client could inform DIQC B.V. that adequate measures have been taken and this action needs to be taken within three consecutive months from the date of suspension. DIQC B.V. conducts an assessment to make the necessary decision.
- 6.1.6 At completion of the specified period of three consecutive months, the Operations Head/Director Operations may:
- a) Remove the suspension and notify the client accordingly or
  - b) Withdraw the certificate, if the conditions have not been fulfilled or
  - c) Reduce the scope of certification to exclude the parts not meeting the requirements, when the client has not been able to meet persistently the certification requirements of the specific part/process of the scope of certification. However, any such reduction is in line with the certification requirements i.e. recommendation by

	<b>Dutch Institute of Quality Certifications</b>	<b>Document no.</b>	<b>D-MMS-S-0016</b>
		<b>Rev. No</b>	02
	Suspension, Withdrawal or Reduction in scope of Certification	<b>Date</b>	07-01-2024

nominated lead auditor for the audited client and subsequent approval by Operations Head/Director Operations.

## 6.2 Withdrawal

6.2.1 DIQC withdraws the certificate and cancels any agreement for use of the certification mark in the following cases:

- a) If additional audit carried out related to suspended client still indicate that non-conformance(s) to relevant requirements are of a serious nature or not actioned upon.
- b) The suspended client does not allow the pending surveillance audit to be conducted within the suspension period of three months
- c) At the written request (voluntary) from the certified client.
- d) The client fails to comply with the due settlement of financial obligation of DIQC, even after the end of suspension period of three months.

6.2.2 DIQC ensures enforceable arrangements with the certified client concerning conditions of withdrawal, duly ensuring the notice of withdrawal of certification that the client discontinues its use of all advertising matter that contains any reference to a certified status.

6.2.3 DIQC makes the withdrawal status of the certification publicly accessible and takes other suitable measures, if it deems appropriate.

Official **Withdrawal Letter** authorized by Operations Head/Technical Head is sent to Client via email.

## 6.3 Scope Reduction

6.3.1 DIQC shall reduce the scope of certification to exclude parts of the certified scope. Certified scope reduction can be done in following scenarios (but not limited to);

- a) The part of scope not meeting the requirements, when the certified client has persistently or seriously failed to meet the certification requirements for those parts of the scope of certification.
- b) Deletion of a product category from the quality management system scope which client organization is no longer manufacturing.
- c) Deletion of activity from scope (e.g. Organization previously certified with Manufacturing and Sales activity may reduce the 'Manufacturing' scope and opt only for 'Procurement and Sales' of product)

A certified client may appeal to DIQC decision making authority against a decision to suspension, withdrawal or reduction in the scope of certification. In case of appeal, the certificate is not suspended, withdrawn or reduced for scope of certification, until the disposal of appeal.

	<b>Dutch Institute of Quality Certifications</b>	<b>Document no.</b>	<b>D-MMS-S- 0016</b>
		<b>Rev. No</b>	<b>02</b>
	Suspension, Withdrawal or Reduction in scope of Certification	<b>Date</b>	<b>07-01-2024</b>

**6.4 Reference to certification and use of certification mark:**

- Organization shall discontinue use of all advertising matter that contains a reference to certification and certification mark when certification is under suspension/ upon withdrawal.
- Organization shall not provide any misleading statement regarding its certification status.
- Organization shall not use or permit the use of a certification document or any part thereof in a misleading manner.
- Organization shall not use its suspended/withdrawn certification in such a manner that would bring the certification body and/or certification system into disrepute and lose public trust.
- Organization shall amend all advertising matter when the scope of certification has been reduced.
- Organization shall not imply that the certification applies to activities and sites that are outside the scope of certification.

**6.5 Return/deletion of certificate and certification mark:**

Upon withdrawal of certification, client shall stop use of all digital copies of certificate, reference to certification and certification mark.

The physical copies of the certificate shall be returned to DIQC B.V. within 1 month from date of withdrawal.

**6.6 Cooperation with the regulatory authorities:**

- DIQC BV is entitled to maintain and publish a register of all Organization holding a current DIQC BV certification. This publication contains the name and address of the certified organization as well as the scope and reference standard and certification status. Organization hereby consents to the publication of such information hereunder as well as to the publication of the same data into mandatory national and international databases managed by country authorities, accreditation bodies or program owners. Additionally, in the course of order processing customer data are stored and processed in external databases of scheme owners. The Organization agrees with the acceptance of the offer that customer data can be stored, accessed and viewed by third parties in the corresponding databases.
- The Organization is obliged to inform DIQC BV immediately of any changes, which may influence the certified management system, processes or the certified products. This applies in particular to the purchase/sale of all or a portion of the Organization, any change in ownership, major changes in operations, fundamental alterations in processes, incidents such as a serious accident or a serious breach of regulation/legal obligation necessitating the involvement of the competent regulatory authority, or the filing for bankruptcy or composition proceedings. In any of these cases, DIQC BV will consult with Organization and determine how the certificate may be maintained.

	<b>Dutch Institute of Quality Certifications</b>	<b>Document no.</b>	<b>D-MMS-S-0016</b>
		<b>Rev. No</b>	<b>02</b>
	Suspension, Withdrawal or Reduction in scope of Certification	<b>Date</b>	<b>07-01-2024</b>

- The Organization is obliged to immediately notify DIQC BV in case of a product recall. The individual certification standards and their regulations use different time frames in terms of meeting this deadline. These specifications can be found in the respective standards and their applicable regulations.
- The DIQC BV acknowledges and agrees that, in certain circumstances, it may be obligated to share necessary information with relevant regulatory authorities of the country in which the certified organization operates. This obligation arises when specific regulatory requirements or legal mandates necessitate the disclosure of information pertaining to the certification process, findings, or any other relevant details.
- In the event that the DIQC BV is required to share information with regulatory authorities, the certified organization shall be promptly notified of such requirements. Notification will be communicated to the certified organization in writing, indicating the nature of the information to be shared, the relevant regulatory authority, and the legal or regulatory basis for such disclosure.
- The DIQC BV shall only share information that is explicitly required by applicable laws, regulations, or official directives. The scope of shared information will be limited to what is necessary to fulfill the legal or regulatory obligations imposed on the DIQC BV.
- The DIQC BV acknowledges the sensitive nature of information related to the certification process. It commits to exercising due diligence in maintaining the confidentiality of shared information to the extent permitted by law. The DIQC BV shall, to the best of its ability, seek to protect proprietary or confidential aspects of the certified organization's information.
- Information sharing will be conducted in strict accordance with applicable laws and regulations. The DIQC BV shall adhere to all legal requirements governing the disclosure of information to regulatory authorities, ensuring compliance with data protection and privacy regulations.
- Prior to sharing any information with regulatory authorities, the DIQC BV will, wherever possible and legally permissible, consult with the certified organization. This consultation may include discussions on the necessity of information sharing, the type of information to be disclosed, and any potential implications.
- The DIQC BV is committed to timely and transparent communication with the certified organization regarding information sharing obligations. Any communication related to information sharing will be clear, concise, and provided within a reasonable timeframe to allow the certified organization to respond or seek legal counsel if necessary. Please note the timeframe shall be less than that provided by the authority.
- The DIQC BV shall not be held liable for any legal consequences arising from the sharing of information as required by applicable laws or regulatory directives. The certified organization acknowledges and accepts that the DIQC BV is bound by legal obligations that may necessitate information disclosure.

	<b>Dutch Institute of Quality Certifications</b>	<b>Document no.</b>	<b>D-MMS-S- 0016</b>
		<b>Rev. No</b>	<b>02</b>
	Suspension, Withdrawal or Reduction in scope of Certification	<b>Date</b>	<b>07-01-2024</b>

**7. Associated Procedures/Documents/Formats**

- 7.1 F-0016-01 Suspension Letter
- 7.2 F-0016-02 Withdrawal Letter