

Title: Procedure for Suspension, Withdrawal or Scope Reduction				
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ECI Management Certification Services LLP

Medical Device Quality Management System

ISO 13485

ECI/P-14

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1. PURPOSE

To detail the procedure for suspension, withdrawal or reduction in scope of certification.

2. SCOPE

All certified clients by ECI – Management System Certification Schemes

3. REFERENCES

- ISO 17021-1
- IAF MD 9

4. RESPONSIBILITY

CEO, and all personnel of ECI.

5. PROCEDURE

5.1 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, but not limited to:
- An improper use of ECI certification mark and/or Accreditation Mark (as permissible)
 - A situation, where a major NC is raised during any surveillance audit and not resolved within stipulated time
 - A situation, where any major changes have taken place in the legal status, ownership, name etc without prior information to the ECI.
 - A situation, where excessive or serious complaints against the certified client management system are received and are found to be valid

Note:

- ECI shall issue due notice of at least one week to the certified client for suspension of certification on above aspects.
 - ECI shall request client for providing Surveillance or Recertification audit dates 2 months prior due date followed by two reminders. In case the client fails to provide audit, date suspension letter shall be issued.
- b) the certified client does not allow surveillance or recertification audits to be conducted at the required frequencies;
- c) The certified client has voluntarily requested a suspension.
- d) The client fails to comply with the due settlement of financial obligation.

Certification is suspended for a period not exceeding six consecutive months under the authority of CEO

Official Suspension Letter is sent E-mail. This letter instructs the client to discontinue use of all advertising matter that contains any certification claim/matter, Certification mark, Accreditation mark till the suspension is lifted.

Under suspension, the client's management system certification is temporarily invalid. ECI 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. ECI makes the suspended status of the certification publicly accessible and takes other suitable measures, if it deems appropriate.

ECI can make the status of given certification available upon request.

At completion of the specified period of six consecutive months, the CEO either

- Remove the suspension and notify the client accordingly or
- 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 of the scope of certification. However, any such reduction is in line with the certification requirements i.e. recommendation by nominated lead auditor for the audited client and subsequent approval by CEO.

5.2 Withdrawal

ECI 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 six 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 ECI, even after the end of suspension period of six months.

ECI 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.

ECI can make the status of given certification available upon request.

Official Withdrawal Letter authorized by CEO is sent to Client by registered post.

For any Suspension or withdrawal an mail shall be sent to client before

Decision for Suspension and Withdrawal

Certification Decision maker is responsible to take the decisions on suspension or withdrawal of certification. The Decision making shall be recorded in Certification decision report ECI/F-16.

5.3 Return of Certificate

The client is reminded of his obligation towards withdrawal of the certificate and shall require to return of the certificate in case of withdrawal.

6. RECORDS

- Suspension Letter (ECI/F-35)
- Withdrawal Letter (ECI/F-36)
- Certification Decision Report (ECI/F-14)

7. REVISION HISTORY

Rev. No.	Effective Date	Details
00	01.01.2025	Initial Issue
01	10.11.2025	Change in the Company Name

