

## Introduction

If an EN ISO 13485 Medical Devices QMS and/or EU 2017/745 Medical Devices Regulation certificate holder fails to comply with the requirements, NOTICE will notify the client about potential repercussions. Failure to meet specified conditions and deadlines may lead to either the suspension or withdrawal of the certificate. While the certificate is suspended, the client is prohibited from claiming adherence to the applicable standard.



**Scope Reduction**

Limiting the scope of the certificate to the extent the compliance with requirements is met.



**Suspension**

Temporary cancellation of a certificate.



**Withdrawal**

Permanent cancellation of a certificate.

## 1. Scope Reduction

NOTICE may narrow the certification scope in the following cases:

- The client ceases to provide part of the services or products within the scope of certification;
- The client fails to resolve the issues that have resulted in the suspension in a defined timeline and this situation affects only parts of the certification scope;
- The client exhibits continuous or severe failure to meet the certification requirements for a part of the certification scope;
- The clients request the reduction of scope.

## 2. Suspension

NOTICE may initiate the suspension process in the following cases:

- Customer voluntary request;
- Vigilance notifications and recalls;
- Delay in resolving open non-conformities;
- The certificate and certification markings are not used in the proper way;
- Justified complaints by third parties;
- The requirements of the certification scheme are no longer met;
- Substantial changes without notification;
- Change of ownership or management, without notification;
- Surveillance audits are not allowed to be conducted according to the required frequency or as scheduled;
- Breaching the agreement with NOTICE;
- Failure to fulfil financial obligations to NOTICE;
- Detection of falsified documents;
- In case of sanctions placed on the company's origin country in the related sector;
- Any other reason indicating the system/products are no longer in compliance with the requirements of the certification scheme.

Suspension of a certificate is initiated as the first step, followed by withdrawal if the issue of concern is not resolved within due time. Dependent on the seriousness of the case, NOTICE may decide a direct withdrawal of the certificate.

The decision to suspend a certificate is communicated to the client by a formal letter.

A certificate shall not be suspended for more than 6 months.

Once the reason for the initial suspension has been rectified (within four months from the suspension date), and verified by NOTICE, the certification will be reinstated after the committee decision on lifting the suspension. The client is informed of the reinstatement decision through an official letter.

## 3. Withdrawal

Withdrawal of certificates initiates when;

- The client requests the withdrawal of the certificate;
- The certification is suspended for a period longer than 6 months;
- The certificate has become invalid because the client has transferred to another Notified Body;
- The client goes bankrupt or terminates its activities;
- The client ceases to provide the services or products within the scope of certification;
- The certificate and certification markings are not used in the proper way
- Use of falsified documents are detected;
- The client fails to meet service agreement with NOTICE;
- A discrepancy between manufactured devices or samples from the market and the specifications specified in the approved technical documentation of the device or the approved device design occurs.

The decision to withdraw a certificate is communicated to the customer including the requirements to:

- Terminate use of the certification mark and any reference to certification;
- Return certificate(s) and copies to NOTICE.

For customers with withdrawn certificate who wish to have the certificate back, the whole certification process shall be started over.

The customer has a right to appeal the decision taken by NOTICE. An appeal can be filed through the SI.FR.24.01 - Customers' Complaint, Appeals & Suggestions Form available on our website.

### **Contact Information**

NOTICE d.o.o.

Room 207, 208, World Trade Centre, Dunajska cesta 156, 1000  
Ljubljana – Slovenia

**Email:** [info@notice.si](mailto:info@notice.si)

**Website:** [www.notice.si](http://www.notice.si)

