Process Description Cooperation Procedure for Approvals in Ukraine

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ID: 7857

1. Introduction

The subject of this process description is the recognition of audit and test reports of mdc medical device certification GmbH (hereinafter "mdc") by the Ukrainian Notified Bodies Improve Medical LLC and UNI-CERT LLC for the approval of medical devices and in vitro diagnostic medical devices in Ukraine.

2. Background

The Ukrainian authority requires manufacturers wishing to place their medical devices on the market in Ukraine to comply with the requirements of the national regulations (Declarations №753, №754 and №755 of the Cabinet of Ministers of Ukraine). These regulations are in line with the EU regulatory framework for medical devices and in vitro diagnostic medical devices. In addition, only products with national conformity marking may be legally distributed in Ukraine.

Through a contractual cooperation with the conformity assessment bodies Improve Medical LLC and UNI-CERT LLC in Ukraine, mdc can support their customers with product registration in Ukraine. The prerequisite for this is that the customer has a valid certificate issued by mdc in accordance with European directives or regulations.

The basis for this cooperation is Article 45 of the Law of Ukraine on "Technical Regulations and Conformity Assessment" (Verkhovna Rada (VVR), 2015, № 14, st.96), which enables the recognition of certification results of European Notified Bodies.

Manufacturers of medical devices or in vitro diagnostics benefit from this cooperation procedure by reducing duplicate auditing or document review, thus reducing time and costs for product approval in Ukraine.

All technical, commercial and scientific information, including trade secrets and proprietary information will be kept confidential under the cooperation procedure.

3. Description of the mdc procedure

Thanks to the recognition of audit and test reports according to European Directives and Regulations by mdc within the framework of the cooperation with the above-mentioned bodies, the need to submit extensive documents on the QM system or technical documents in Ukraine can be avoided under certain conditions.

If the manufacturer wishes to use the cooperation procedure to place his products on the market in Ukraine, he will be informed informally by e-mail of the expected costs. The order is also placed informally by e-mail.

The usual course of a certification procedure according to the rules for certification procedures according to Regulation (EU) 2017/745 underlying the application remains unaffected by this procedure.

The order comprises exclusively the preparation of the confirmation letter and the provision of the required assessment reports and, if necessary, once a year for a new confirmation letter. The aforementioned service shall be invoiced according to our price list for certifications according to Regulation (EU) 2017/745. Existing reports in English are assumed. If German has been agreed as the language of the report, translation costs will be charged in accordance with the price list. Translations provided by clients will not be accepted by mdc.

Before the start of the cooperation procedure, a declaration of consent must be obtained from the client for the exchange of information between mdc and the body involved in the cooperation procedure.

A prerequisite for the recognition of the mdc certification by the body involved in the cooperation procedure is the submission of a confirmation letter issued by mdc. The client adds to this a copy of the certificates concerned in English as well as a copy of the confirmed audit/test reports in English and a cover letter written by him to the cooperation partner.

Communication with the cooperation partner or with the Ukrainian authorities is not routinely provided for. If this is necessary, remuneration is based on time and effort at the current daily rate according to our price list for certifications according to Regulation (EU) 2017/745.

The auditing of national Ukrainian requirements is not required. The aforementioned documents are submitted by the client to the body involved in the cooperation procedure.

According to the contract concluded between mdc and the cooperation partners, further documents and reports can be requested from the manufacturer within the framework of the conformity assessment procedure. The cooperation partner can also request these documents directly from mdc. Since a declaration of consent for data exchange is available, mdc can provide the requested documents to the cooperation partner without further consultation with the customer.