Description of the procedure to support product registration in Ukraine

CONTENT

If you should require any further information then please do not hesitate to contact us. We will be please to help you.

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TÜVNORD

Description of the procedure to support product registration in Ukraine

SHORT DESCRIPTION

Through a contractual cooperation with Ukrainian conformity assessment bodies, TN CERT can offer existing customers with a valid certificate in accordance with the Medical Devices Directive 93/42/EEC support for product registration in Ukraine.
This cooperation is based on Article 45 of the Law of Ukraine on "Technical Regulations and Conformity Assessment" (Verkhovna Rada (VVR), 2015, № 14, st.96), which allows the recognition of certification results of European Notified Bodies.

1. PROCESS DESCRIPTION

1.1. Precondition to carrying out the procedure

This service can only be offered to TN CERT customers who have a valid certificate issued by TN CERT in accordance with the Medical Devices Directive. (hereinafter referred to as "Customer")

1.2. Initial registration procedure

- The customer submits an application for conformity assessment to one of the conformity assessment bodies contractually associated with TN CERT in Ukraine (hereinafter referred to as CAB).
- The CAB in the Ukraine sends documents for conformity assessment to the customer.
- The Customer commissions TN CERT - as Notified Body in the EU - to forward certification evidence to a CAB in Ukraine contractually connected with TN CERT.
- TN CERT prepares an extension offer to the contract already agreed with the customer for conformity assessment in accordance with the Medical Devices Directive.
- TN CERT transfers a letter of confirmation and defined supporting documents, which led to the certification of the company, to the Ukrainian CAB.
- Examination of the TN CERT documents by the CAB in Ukraine and - if positive - recognition of the conformity assessment and registration of the products of the TN CERT customer in Ukraine

1.3. Audit Stage Procedure after initial registration

- The maintenance of the registration for the Ukrainian market takes place via an annually repeated order by the customer to TN CERT.
- After the order has been placed, TN CERT forwards the required proof documents and the letter of confirmation for the previously performed surveillance or recertification audit to the CAB in Ukraine.
- The further procedure corresponds to that for initial registration

2. INFORMATION TRANSMISSION

- The necessary documents are transferred from TÜV NORD CERT to the CAB in the Ukraine (unless otherwise agreed) via File Exchange (pdf files).

- After completion of the transfer, TÜV NORD CERT will inform the client of this by e-mail

3. EXTENSION OF THE CERTIFICATE OF CONFORMITY EXTENSION OF SCOPE AUDIT

- In case of an extension of the existing certificate of conformity due to additional products, a new order is mandatory. The procedure is identical to the initial registration.

4. CHANGES TO THE STATUS OF CONFORMITY CERTIFICATE ACCORDING TO 93/42/EEC

- Any change in the status of the conformity assessment certificate according to 93/42/EEC (suspension, suspension, modification of certified products etc.) will be forwarded by TN CERT to the CAB in Ukraine. This can have an impact on the product registration in Ukraine. The CAB in Ukraine will contact the manufacturer (TN CERT customer) in this regard.

- If TN CERT completely withdraws the conformity assessment certificate according to 93/42/EEC, the obligation of TN CERT for this service automatically expires.