Product Service

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Med-Info

International expert information for the medical device industry

Medical devices for the US and Canada – NRTL and FES, the visa for market access

To market technical products for use in public buildings or in workplaces in the US and Canada, they must be tested, certified, and labelled by an accredited entity. This applies particularly to all electrically controlled medical devices and systems.

The approval of electrically controlled devices and systems is regulated by Articles 90.7, 110.2, and 110.3 of the National Electric Code (NEC) – comparable to Article 2-024 of the Canadian Electrical Code (CEC) and Article 29 CFR 1910.301 (Subpart S) of the Occupational Safety and Health Administration (OSHA). European certification marks are not recognised.

Possibilities for approval

- **Products produced and sold unchanged in large quantities may be listed through a certification by a Nationally Recognized Testing Laboratory (USA) or certification body (Canada).** TÜV SÜD is authorised as a Nationally Recognized Testing Laboratory (NRTL) through recognition by OSHA in the US and the Standard Council of Canada (SCC) in Canada.

- **For products that cannot be NRTL-certified or for which a NRTL certification would be too costly (e.g. custom-made products, small quantities, products already installed on location), it is possible to apply for an individual approval in the context of the Field Evaluation Service (FES) or the CSA model code SPE 3000 for medical electrical equipment (MEE) or medical electric systems (MES) for the Canadian market.** The locally responsible Authority Having Jurisdiction (AHJ) approves the system on the basis of the field label and the accompanying report. TÜV SÜD is recognised by many AHJs.

1. Nationally Recognized Testing Laboratory (NRTL)

The basis for a NRTL certification of medical devices is the testing of electrical and mechanical safety. If this testing, with the appropriate national differences, has already been carried out by an entity that is a member of the IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE; CB Scheme) then the testing will be acceptable. Other supplementary national requirements as well as EU-relevant standards are tested by our test lab.

You can choose from three options

- **NRTL US**
  Based on requirements of
  ANSI/AAMI ES60601-1:2005/(R)2012
- **NRTL C+US**
  Based on requirements of
  ANSI/AAMI ES60601-1:2005/(R)2012 and
  CAN/CSA-C22.2 No. 60601-1:2014
- **NRTL C**
  Based on the requirements of CAN/CSA-C22.2
  No. 60601-1:2014

Before certification of the product, the NRTL must conduct an initial inspection of the production site. The certification is then sustained by means of regular production site inspections. The frequency of these inspections is determined in the course of certification and, depending on the risk potential of the product and the trustworthiness of the quality management (QM) system, can be two to four times a year.
After certification, the manufacturer can put the certification mark of the NRTL on the product, thus indicating that it has the necessary certification.

Rollover

If you already have NRTL certificates for some of your products from other entities (i.e. UL, CSA, etc.) and would like to utilise our competence as sole external entity, TÜV SÜD is happy to take over your existing NRTL certifications and transfer them to our TÜV NRTL mark via our rollover procedure.

Your advantages

- You can cover your complete product range by the production site inspections of one entity.
- If you are already a client for system certification you can combine the annual audit with one of these annual factory inspections to increase efficiency while lowering costs.
- You work together with only one company for system certification, product testing, and worldwide product approvals.

2. Individual acceptance procedure – USA and Canada: Field Evaluation Service (FES)

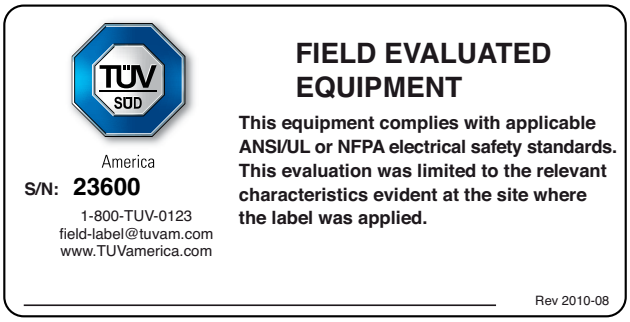
An individual acceptance procedure can be considered for

1. devices
- that are not manufactured repeatedly.
- that are manufactured for a special application (special production models).
- that are manufactured and sold in small numbers.
- that are not covered by other certification programs.
- that are installed on-site and wait for approval by the appropriate authorities.
- that have undergone an acceptance procedure on-site, but have been modified or moved since that time.
- that are already certified, but have subsequently been altered.
- that are first exported to the US in small quantities for market evaluation only and for which a certification would be too complex and costly.

2. complete systems, the individual components of which have been approved, but not yet as a unity.

In order to complete the approval process as quickly and simply as possible, we offer you the option of doing a partial or complete acceptance procedure for your system while it is still in Germany, so that any necessary modifications can be carried out under your direction at your own production sites. For equipment that is plugged into an electrical outlet, the complete acceptance procedure can be carried out in Germany. For devices that have a fixed connection to the power network, it is necessary to combine a preliminary evaluation in Germany with a final acceptance procedure at the site of installation in the US.

A device that has undergone a preliminary or complete acceptance procedure is marked with a numbered field label.



Advantages

1. Avoidance of approval problems from local AHJ inspectors and thus:
   - on-time system start-up,
   - no costs due to necessary modifications in the US.

2. In the case of an industrial accident
   - An evaluation can reduce the occurrence or cost of a workplace injury and/or employee downtime.

Your contact partner at TÜV SÜD Product Service can provide further information.

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