



Product Service

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Med-Info

International expert information
for the Medical Device industry

Medical products for America and Canada – NRTL and FES, the visa for market access

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

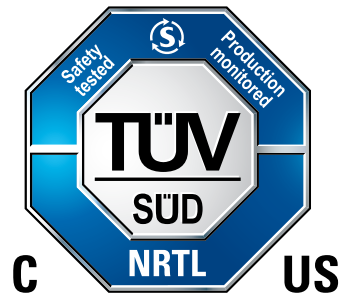
The approval of electrically controlled devices and systems is regulated by Articles 90.7, 110.2, and 110.3 of the National Electric Code (NEC) – comparable to Article 2-024 of the Canadian Electrical Code (CEC) and Article 29 CFR 1910.301 (Subpart S) of the Occupational Safety and Health Administration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

Possibilities for approval

- **Products, produced and sold unchanged in large quantities, are listed through a certification by a Nationally Recognized Testing Laboratory (USA) or certification body (Canada).** TÜV SÜD Product Service is authorized as a Nationally Recognized Testing Laboratory (NRTL) through accreditation by OSHA in the USA and the Standards 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. special production models, small quantities, already installed on location), it is possible to do an “individual approval” in the context of the so-called Field Evaluation Services (FES). This excludes Canada.** The locally responsible Authority Having Jurisdiction (AHJ) approves the system on the basis of the field label and the accompanying report. TÜV SÜD is accredited by many AHJs.

1. Nationally Recognized Testing Laboratory (NRTL)

The basis for a NRTL certification of medical products is the testing of electrical and mechanical safety. If this test has already been carried out, the testing is acceptable if the testing entity is a member of the "Worldwide System for Conformity Testing and Certification of Electrical Equipment" (IECEE; CB Scheme). Other supplementary national requirements as well as EU-relevant standards (in the case of a CUE mark) are tested by our test lab.



You can choose from three options

- **NRTL US**
Based on requirements of UL 60601-1.
- **NRTL C+US**
Based on requirements of UL 60601-1 and CAN/CSA-C22.2 No. 601.1-M90.
- **NRTL CUE**
Based on NRTL C+US, the European requirements can be tested on a voluntary basis in accordance with an internal TÜV PS testing program.

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 QM system, can be two to four times per 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

You already have NRTL certificates for some of your products from other entities (UL, CSA, etc.) and would like to utilize our competence as sole external entity? We are happy to take over your existing NRTL certifications and transfer them to our TÜV NRTL mark in a rollover procedure.

Your advantages

- You can cover your complete product range by the production site inspections of one entity.
- If you are already a customer in the context of a system certification, the annual audit can be combined efficiently and cost-effectively with one of these production site inspections.
- You work together with only one company for system certification, product testing and worldwide product approvals.

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

An individual acceptance procedure can be considered for

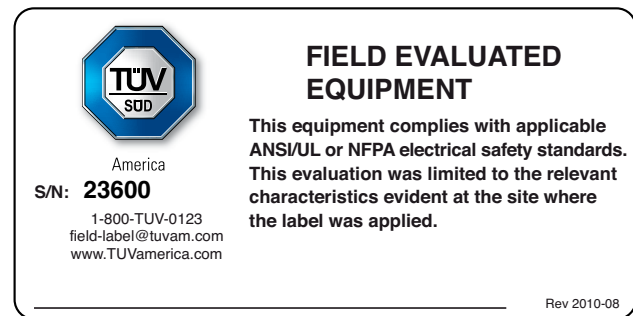
1. Devices

- 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 USA 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 USA.

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 USA.

2. In the case of an industrial accident, no complications in a legal controversy in the respective courts due to improper approval.

More information on the procedure is available on the Internet at www.tuev-sued.com/medinfo.

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

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