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Cables with the Right Style

Certified components | When manufacturers of medical devices want to sell their products in North America, the suppliers of the components also need to be qualified. For example, when installed cables are UL listed or recognised, this simplifies and accelerates the certification processes.

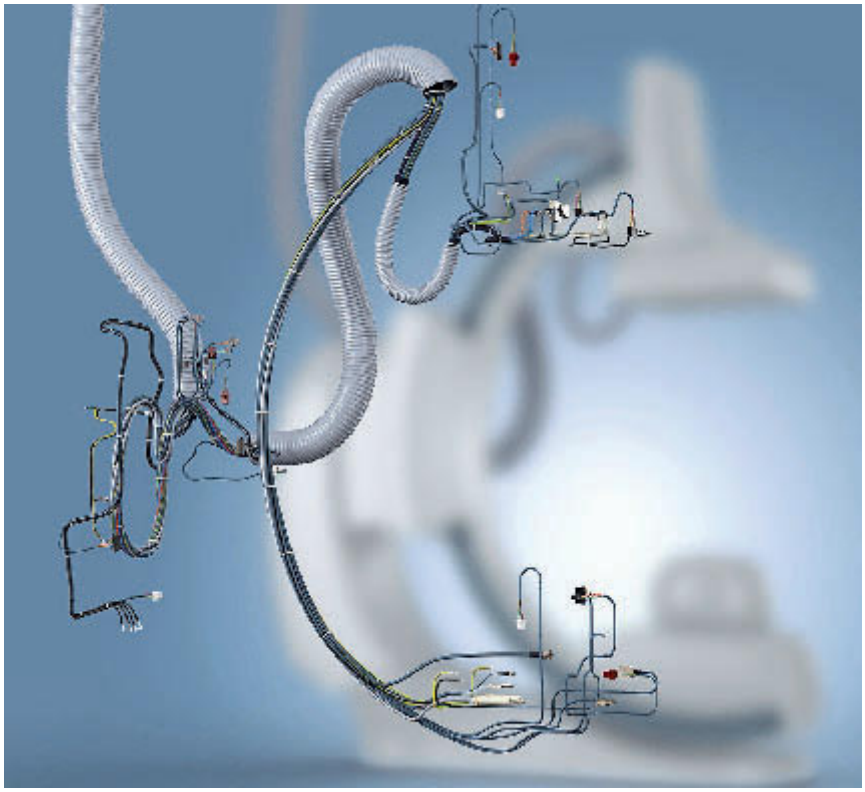

Photo: Leoni

Different use, different rules–cables have to meet special requirements that change depending on whether cables are used in the device or outside of the device.

VDE, IEC, ISO, CE, USP, UL, CSA, AWM, NEC, FDA–all of these touch on only a small part of the many standards and ratings for medical devices. These standards and ratings are important when medical devices are sold internationally. Different applications are subject to different guidelines that have to be met by all suppliers for the respective application.

It can be easy to lose sight of the big picture just with the approvals for cables in the modern OR: whilst UL standard 758 for Appliance Wiring Material (AWM) applies to cables within a medical device, the cables installed permanently in a building must be listed according to various other UL safety standards and, most importantly, they must comply with the applicable articles of the National Electrical Code (NEC). For medical cables that touch the patient directly, UL is often secondary, however. Biocompatibility guidelines, such as DIN ISO 10993, USP, and FDA, take precedence for these cables. In addition, all cables must be optimised electrically, mechanically, thermally, and chemotechnically for their use and, last but not least, they must conform to the design requirements of the manufacturer.

Whilst VDE and IEC are the minimum requirements for medical technology devices in Germany and Europe, the UL and CSA specifications for the North American market follow a stricter set of rules. These specifications have meanwhile become a measure for product safety in many other countries as well, however.

For instance, system supplier Leoni provides UL-listed wiring harnesses for the Artis zee angiography system from Siemens Healthcare. The wiring harnesses are used for the monitor and system cabling and for the patient table. Since the cable specialist was involved early on in the development process, the right cables were defined in the bills of material (BOMs) and specifications (specs) and some were even specially redesigned. This simplifies and shortens the certification processes. BOMs as well as specs are in compliance with the operating conditions and with the design requirements from Siemens and the applicable UL styles.

Detailed codes for various applications

This compliance is important because the defined design of the cables installed in the devices must match an existing standard: what is stated in general in the UL codes is listed in more detail for each application in AWM styles. A cable manufacturer recognised by UL can qualify for different style numbers and may then label the respective cables from its range of products with the “UL recognition mark” for recognised components.

YOUR KEYWORDS

- Selection of suitable cables
- Internationally applicable standards for various applications
- Cooperation with experts in the early development phase
- Use of certified components

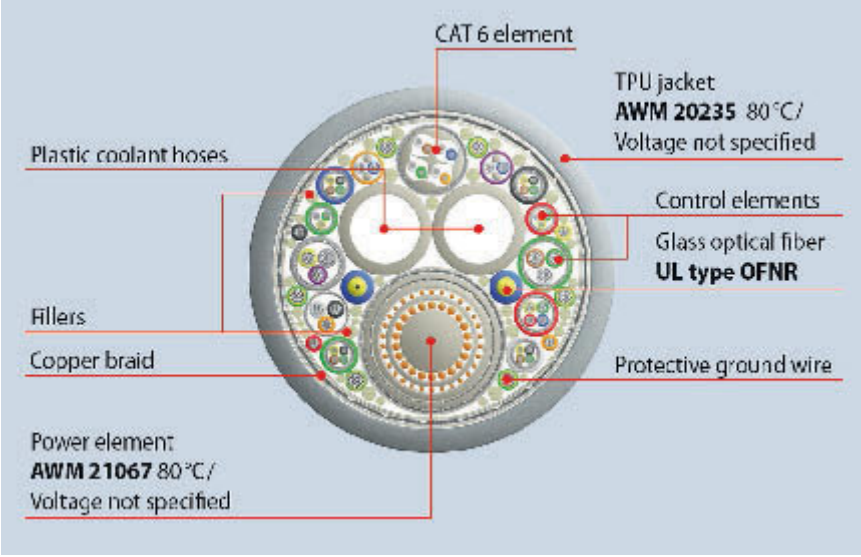

Photo: Leoni

This cross-section shows examples of possible elements of a Leoni hybrid cable that meets the requirements for a "UL-recognised component for external use."

Cables that belong to such a AWM style must be used in the applications according to the style description. This description contains information on the rated voltage in volts, the maximum allowable continuous use temperature at the conductor in degrees Celsius, the conductor materials and size (in AWG), and flammability class. Even insulation and cladding materials must be specified with the permitted nominal wall thickness in mils (thousandths of an inch) or millimetres.

In the device is not on the device

Therefore, it is important to make sure in the development phase that the basic conditions of the possible UL style for the cable match the actual usage conditions. This is what happens with Artis zee: whilst the internal cables of the C-arm module consist largely of "UL-recognised components for internal use," the accessible cables fall under "UL-recognised components for external use." The cables have different electrical parameters and are also different in regard to the flame resistance of the cable jacket, which is possible through the selection of appropriate materials and the overall diameter. Close to 8,000 UL styles are divided into internal and external wiring. Cables from Leoni cover almost 800 of them. The stricter standard does not always have to be the right one here.

For a wiring harness to be listed as a "UL wiring harness," the qualified supplier must have UL examine and approve the complete design of a wiring harness to guarantee traceability. Random sampling ensures that wiring systems are manufactured exactly how they are described in the BOM and specs.

If a radiology device is connected to endoscopic devices, catheters, or other instruments used in the OR, the cables for the devices usually have to be, most importantly, sterilisable and biocompatible. This also applies to all cables that come into direct contact with patients. Here, the extent of risks coming from the material, a dye, or an additive in the cladding are inspected. Based on the type and duration of application, there are 20 different risk assessments for DIN ISO 10993 and 6 classes of the United States Pharmacopeial Convention (USP). The FDA also analyses the compatibility of a cladding material.

Leoni manufactures cables and cable systems for medical devices using various cladding substances. New material mixtures and wiring designs are tested, at the client's request, by accredited testing laboratories for biocompatibility in compliance with DIN ISO 10993. ■

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