CIM med - a Medical Device Risk Class 1 - Learn why!

General information on CIM med mounting solutions

CIM med offers specialized mounting solutions tailored for the medical industry. These solutions are designed to meet the stringent requirements of the medical field, particularly in terms of regulatory compliance.

CIM med mounting solutions are classified as medical product risk class 1, adhering to the guidelines of (EU) 2017/745 (MDR) and IEC 60601-1. CIM med is not only FDA registered but also fully compliant with the relevant FDA regulations for medical product risk class 1 devices.

Medical products in Europe and the USA

In the context of medical devices, regulations vary between Europe and the USA. In Europe, manufacturers need a CE mark following the EU Medical Device Regulation (MDR 745/2017), while in the USA, clearance or approval from the US Food and Drug Administration (FDA) is required. Irrespective of the market, manufacturers must adhere to the applicable Quality Management System standards or regulations.

For the USA, Quality Management System Requirements are detailed in 21 CFR Part 820, whereas in the EU, adherence to the Quality Management System for Medical Device Standard ISO 13485:2016 is mandatory. CIM med aligns with both Quality Management Systems as outlined in our Quality Management Manual.

Regulatory controls and marketing pathways in both regions are determined by the device's risk level to ensure safety and effectiveness are maintained at all times. Compliance with these regulations is crucial to provide a reliable and safe product for the medical industry.

Applicable laws and regulations in the EU

In Europe, the classification of medical devices and medical device-related accessories is defined in the MDR, Chapter 1 Scope and Definitions, Article 2 Definitions. The below extract refers to the relevant definition and criteria for the classification of CIM med mounting solutions.

<u>MDR Chapter 1- Scope and Definitions - Article 2 - Definitions</u>

“For the purposes of this Regulation, the following definitions apply:

(1) ‘medical device’ means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: …

The following products shall also be deemed to be medical devices:

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(2) ‘accessory for a medical device’ means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s);”

Applicable laws and regulations in the US

In the US, the classification of a medical device is governed by FDA laws and regulations. The FDA Guidance on Medical Device Accessories and Classification Pathways outlines the criteria for defining an "accessory" and the classification processes under Section 513(f)(6) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). This guidance enables requests for risk- and regulatory control-based classification of accessories. The following extract of the guidelines addresses the classification of the CIM med mounting solutions:

FDA Medical Device Accessories - Describing Accessories and Classification Pathways - Guidance for Industry and Food and Drug Administration Staff - V. Accessory Classification Policy - A. Is the article an accessory?

“We consider an accessory as an article that:

1. Is intended for use with one or more parent devices. FDA expects that whether an article is intended for use with a parent device will generally be determined by the labeling and promotional materials for the potential accessory device (rather than by the labeling and promotional materials for the parent device)…
2. Is intended to support, supplement, and/or augment the performance of one or more parent devices. A device supports the performance of a parent device by enabling or facilitating that device to perform according to its intended use… The accessory is necessary to enable the parent device to meet its intended use. An infusion pump stand also supports the intended use of a parent device (an infusion pump) by holding medications or liquids and other infusion accessories firmly, at an appropriate height, and in convenient reach of the patient or caregiver. In this case, the parent device can perform its intended use without the accessory, but the accessory nonetheless supports the performance of the device.”

Medical device databases

In the EU and the US, distinct medical device databases operate to store crucial information such as the device class and Intended Use. The FDA manages the medical device database in the US, while EUDAMED serves this purpose in the EU. These databases function independently of each other.

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