Compatibility of our CIM mounting arms with anaesthesia machines

Legal requirements

The following chapters of the consolidated version of the regulation (EU) 2017/745 on medical devices (MDR) of 5 April 2017 are relevant for the mounting CIM support arms to anaesthesia machines:

Chapter 1: Scope and definitions / Article 2: Definitions

(25) ‘Compatibility’ is the ability of a device, including software, when used together with one or more other devices in accordance with its intended purpose, to:

(a) perform without losing or compromising the ability to perform as intended, and/or

(b) integrate and/or operate without the need for modification or adaption of any part of the combined devices, and/or

(c) be used together without conflict/interference or adverse reaction.

Annex I: General safety and performance requirements / Chapter 2: Requirements regarding design and manufacture

14. Construction of devices and interaction with their environment

14.1. If the device is intended for use in combination with other devices or equipment the whole combination, including the connection system shall be safe and shall not impair the specified performance of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use. Connections which the user has to handle, such as fluid, gas transfer, electrical or mechanical coupling, shall be designed and constructed in such a way as to minimise all possible risks, such as misconnection.

14.2. Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible:

(a) the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;

(b) risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences;

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(c) the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during normal conditions of use;

d) …

(e) the risks of accidental ingress of substances into the device;

(f) the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given; and

g) …

14.3. …

14.4. Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively.

14.5. Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.

14.6 Any measurement, monitoring or display scale shall be designed and manufactured in line with ergonomic principles, taking account of the intended purpose, users and the environmental conditions in which the devices are intended to be used.

14.7. Devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substances by the user, patient or other person. To that end, manufacturers shall identify and test procedures and measures as a result of which their devices can be safely disposed after use. Such procedures shall be described in the instructions for use.

Statement

All CIM products undergo rigorous testing procedures in line with the regulations and guidelines of (EU) 2017/745 (MDR) and IEC 60601-1. These tests encompass weight load assessments, static and dynamic evaluations, all conducted on the respective anesthesia machine. We thoroughly consider the specifications and limitations set by the device manufacturers during our assessments.

All tested CIM products and configurations in connection with anesthesia machines from the manufacturers Dräger, GE, Getinge, Löwenstein and Mindray are available as a download catalog on our website https://cim-med.com/solutions/anaesthesia

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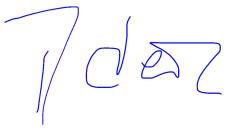
Our recommendation

We strongly recommend to opt for tested and compliant solutions exclusively. Utilizing non-tested products places the onus on the distributor or healthcare facility to verify the compatibility of the combination, perform necessary test series, and ensure adherence to safety standards and regulations.

Munich, 10th March 2025



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