EU Quality Management System Certificate FI24/00000026

The management system of

pfm medical hico gmbh

Address: Wankelstr. 60, 50996 Köln, Germany. SRN: DE-MF-000012921

has been assessed and certified as meeting the requirements of

Regulation (EU) 2017/745 Annex IX (I, III, and TDA in Section 4)

For the following products
Body thermoregulation equipment

Certification is based on FI24/08143P0
Previous certificate number: N/A
Change in between this certificate and previous one: N/A
Devices covered, their intended purposes, risk classification, standards and common specifications followed, as well as applicable test and audit reports referred to, are listed on the subsequent pages of this certificate.

This certificate is valid from 18 April 2024 until 17 April 2029 and remains valid subject to satisfactory surveillance audits.
Issue 1 Certified since 18 April 2024
Certified activities performed by additional sites are listed on subsequent pages.

Authorised by
Seppo Vahasalo

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Notified Body 0598 Takomotie 8, FI-00380 Helsinki, Finland
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FINAS
Finnish Accreditation Service
S009 (EN ISO/IEC 17021-1)

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Issue 1
Sites
Wankelstr. 60, 50996 Köln, Germany Location of top management
Bonner Str. 180, 50968 Köln, Germany Design and development, production, distribution and maintenance of Hypo- / hyperthermia systems; and maintenance as part of post market activities for pfm medical hico products

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Attachment 1 of Issue 1

Device or Device Group, EMDN Code	Risk Class	Identification Details and Intended Purposes
EMDN Z12040208 Body thermoregulation equipment	IIb	Hypo- / hyperthermia systems Models: HICO-Variotherm 550, HICO-Variotherm 555, HICO-Aquatherm 660. Intended purpose: The device is intended for patient temperature management in combination with water pads without monitoring the body temperature.

The certification decision is based on the following:

Report Identification and Date
Audit report: pfm - V1S2 - FPMDREG3019 - MD Audit Summary Report Ver E 20240319.pdf dated 2024-03-19 TDA Report: pfm - V1 - 2023 - FPMDREG3020 - MDR Technical Documentation Assessment Report Ver F 20240228.pdf dated 2024-02-28.

Applied Standards / Common specifications
N/A

Conditions for or limitation to the validity of the certificate
N/A

EU Authorised Representative
N/A

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