

EU Quality Management System Certificate

mdc medical device certification GmbH

Kriegerstr. 6, 70191 Stuttgart, Germany Notified body (identification number 0483)

hereby certifies that the company (SRN: AT-MF-000017155)

JOANNEUM RESEARCH Forschungsgesellschaft mbH

Leonhardstraße 59 8010 Graz Austria

has implemented and applies a quality management system in accordance with Annex IX, Chapter I of Regulation (EU) 2017/745 for conformity assessment of the devices listed on the following pages.

An audit by mdc has proven that this quality management system fulfils the following requirements:

Annex IX - Chapter I (Quality Management System)

of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

Surveillance is carried out in accordance with Annex IX, Section 3 of Regulation (EU) 2017/745.

This certificate consists of 2 pages. Details of the devices affected by this certificate as well as further information and conditions are included on the following pages.

Valid from:2022-10-19Registration No.D4004700006Valid until:2027-10-18Evaluation Report No.210446

Stuttgart, 2022-10-19

Benannt durch/Designated by Senannt durch/Designated by Se

Head of Notified Body



Devices:
Product: DEA15005 Dermal catheter
Risk class: Ila
Product: PEB001 Perfusate bag
Risk class: IIa
Product: PSH400 Push 4-channel tubing set
Risk class: IIa
Product: PSH300 Push 3-channel tubing set
Risk class: Ila