

EU Quality Management System Certificate

We hereby certify the company

Robert Helwig GmbH
Zum Technologiepark 6
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Germany

the introduction and application of a quality management system in accordance with Annex IX, Chapter I and III of Regulation (EU) 2017/745 for conformity assessment.

An audit by mdc has proven that this quality management system meets 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 from mdc medical device certification GmbH (Notified Body 0483) consists of 2 pages. Details about the devices covered as well as further information and conditions are contained on the following pages.

Valid from 2025-05-23
Valid until 2030-05-22

Registration No. D1514800003
Report No. P23-01202-278515

Stuttgart 2025-05-23



Notified Body



Devices:

Non-sterile injection, suction and irrigation cannulas made of metal

Risk class: IIa
