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

Philipp Kirsch GmbH

Im Lossenfeld 14
77731 Willstätt
Germany

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

Valid from:	2022-03-28	Registration No.	D1423300013
Valid until:	2027-03-27	Evaluation Report No.	210610

Stuttgart, 2022-03-28

Head of Notified Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-098

Devices:

Product: BL 100 PRO-ACTIVE

Risk class: IIa – not implantable

Product: BL 176 PRO-ACTIVE

Risk class: IIa – not implantable

Product: BL 300 PRO-ACTIVE

Risk class: IIa – not implantable

Product: BL 520 PRO-ACTIVE

Risk class: IIa – not implantable

Product: BL 720 PRO-ACTIVE

Risk class: IIa – not implantable

Product: BL 300 ULTIMATE

Risk class: IIa – not implantable

Product: BL 520 ULTIMATE

Risk class: IIa – not implantable

Product: BL 720 ULTIMATE

Risk class: IIa – not implantable

Product: FROSTER BL 178 PRO-ACTIVE

Risk class: IIa – not implantable

Product: FROSTER BL 180 PRO-ACTIVE

Risk class: IIa – not implantable

Product: FROSTER BL 330 PRO-ACTIVE

Risk class: IIa – not implantable

Product: FROSTER BL 530 PRO-ACTIVE

Risk class: IIa – not implantable

Product: FROSTER BL 650 PRO-ACTIVE

Risk class: IIa – not implantable

Product: FROSTER BL 730 PRO-ACTIVE

Risk class: IIa – not implantable

Product: FROSTER BL 330 ULTIMATE

Risk class: IIa – not implantable

Product: FROSTER BL 530 ULTIMATE

Risk class: IIa – not implantable

Product: FROSTER BL 730 ULTIMATE

Risk class: IIa – not implantable
