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: CH-MF-000024167)

Falco Linsen AG

Talackerstrasse 14
8274 Tägerwilen
Switzerland

EU Authorized Representative: Falco Linsen GmbH, Turmstraße 11, 78467 Konstanz, Germany
(AR-SRN: DE-AR-000018800)

has implemented and applies a quality management system in accordance with Annex IX, Chapter I and III 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:	2023-11-23	Registration No.	D1449900004
Valid until:	2028-09-23	Evaluation Report No.	P23-00247-259724

Stuttgart, 2023-11-23

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:
Rigid contact lenses (RGP); Scleral contact lenses; Orthokeratology lenses

Risk class: IIa