EU Quality Management System Certificate

We hereby certify the company

Medilens Säntis AG
Röschstrasse 18
9000 St. Gallen
Switzerland

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	2024-03-07	Registration No.	D1202000005
Valid until	2028-10-04	Report No.	P23-00284-260341

Stuttgart, 2024-03-07

Notified Body

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

EU Authorized Representative:

Hecht Contactlinsen GmbH
Dorfstraße 2 - 4,
79280 Au bei Freiburg, Germany
DE-AR-000022273

Devices:

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soft contact lenses

Risk class: IIa
