EU Quality Management System Certificate

We hereby certify the company

Gerium Medical Ltd.
4 Paran St., Building 11, PO Box 13271
Yavne 8122503
Israel

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	2026-01-01	Registration No.	D1355800016
Valid until	2028-03-14	Report No.	P24-01470-350534

Stuttgart, 2025-12-18

Notified Body

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

EU Authorized Representative:

AR Experts B.V.
Boeingavenue 209
1119 PD Schiphol-Rijk
Netherlands
NL-AR-000023989

Devices:

BiliCare (non-invasive transcutaneous bilirubinometer)

Risk class: I (measuring function)

BiliWrap (portable phototherapy device used to treat neonatal jaundice (hyperbilirubinemia))

Risk class: IIa

Notes:

For class I devices with a measuring function the involvement of mdc is limited to the aspects relating to the conformity of the devices with the metrological requirements.

The certificate is based on the previous certificate

D1355800013 (2023-03-15)
D1355800015 (2024-10-16)

with the following changes to D1355800015:
Change of authorized representative from CEpartner4U to AR Experts BV