

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: IL-MF-000012189)

Elcam Medical ACAL

Baram 1386000
Israel

EU Authorized Representative: MedNet EC-Rep GmbH, Borkstraße 10, 48163 Münster, Germany
(AR-SRN: DE-AR-000000002)

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:	2023-07-05	Registration No.	D2001100013
Valid until:	2028-07-04	Evaluation Report No.	P22-01802-254236

Stuttgart, 2023-07-05



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:
PureSite Closed Male Connector + Accessories

Risk class: I (sterile)

Notes:

For class I devices placed on the market in sterile condition the involvement of mdc is limited to the assessment of the aspects relating to establishing, securing and maintaining sterile conditions.