

Certificate

We hereby certify the company

Elcam Medical ACAL
Baram, 1386000
Israel

with the sites listed in the attachment the introduction and application of a

Quality management system according to EN ISO 13485

in the scope

Development, design, manufacturing and sales of disposable medical devices for fluids administration, withdrawal, transfusion and pressure monitoring, and of disposable & reusable auto-injectors

An audit by mdc has proven that this quality management system meets the requirements of the following standard:

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016
Medical devices – Quality management systems – Requirements for regulatory purposes

Valid from 2024-06-14
Valid until 2026-07-04

Registration No. D2001100017
Report No. P24-00591-297811

Stuttgart, 2024-06-14



Certification Body



DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16002-06-00

Sites included in the certification:

Location	Scope
Elcam Medical ACAL Baram, 1386000 Israel	Development, design, manufacturing and sales of disposable medical devices for fluids administration, withdrawal, transfusion and pressure monitoring, and of disposable & reusable auto-injectors
Elcam Medical ACAL P.O. Box 9 Dalton Industrial Park, 1381000 Israel	Development, design, manufacturing and sales of disposable medical devices for fluids administration, withdrawal, transfusion and pressure monitoring, and of disposable & reusable auto-injectors

Stuttgart, 2024-06-14



Certification Body