

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, manufacture, distribution and sales of disposable medical devices and components for fluid administration, withdrawal, transfusion, flow control, and pressure monitoring, and manufacture of disposable & reusable autoinjectors

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 2026-07-05
Valid until 2029-07-04

Registration No. D2001100018
Report No. P26-00352-358733

Stuttgart, 2026-06-17



Certification Body



Sites included in the certification:

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

Stuttgart, 2026-06-17



MDC
Certification Body