

# CERTIFICATE

This is to certify that the Quality Management System of  
**ELCAM MEDICAL ACAL**

Kibbutz Bar-Am, 1386000, ISRAEL

Has been assessed and complies with the requirements of :

**ISO 13485:2016**

This Certificate is Applicable to

**Development, design, manufacturing and sales of disposable and reusable medical devices.**



THE STANDARDS INSTITUTION OF ISRAEL



The standards Institution of Israel  
42 Chaim Levanon St,  
Tel-Aviv 6997701

**Initial Approval:**  
**Issue Date:**  
**Valid Until:**

15/12/2003  
03/06/2021  
15/12/2023

**Revised:**  
**Certificate No.:**

06/06/2021  
111404

SII-QCD assumes no liability to any party other than the client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with SII-QCD requirements for system certification. The continued validity may be verified via scanning the code with a smartphone, or via website [www.sii.org.il](http://www.sii.org.il). This certificate remains the property of SII-QCD.

  
Dr. Gilad Golub  
CEO



R.N 570037085

  
Avital Weinberg  
Director, Quality & Certification Division

# Annex to Certificate of Registration no. 111404

## ELCAM MEDICAL ACAL

Kibbutz Bar-Am, 1386000, ISRAEL

With Additional Sites At:

**Dalton site:**

P.o Box 9, 1381000, Israel

**Scope:** Development, design, manufacturing and sales of disposable and reusable medical devices.



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THE INTERNATIONAL CERTIFICATION NETWORK

# CERTIFICATE

**THE STANDARDS INSTITUTION OF ISRAEL**

*has issued an IQNet recognized certificate that the organization:*

**ELCAM MEDICAL ACAL**

Kibbutz Bar-Am, 1386000, ISRAEL

Has implemented and maintains a Quality Management System

For the following scope:

**Development, design, manufacturing and sales of disposable and reusable medical devices.**

which fulfils the requirement of the following standard:

**ISO 13485:2016**

Issued on:	03/06/2021
Date of initial approval:	15/12/2003
Date of expiration:	15/12/2023

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

**Registration number: IL - 111404**



  
 Alex Stoichitoiu  
 President of IQNet

  
 Avital Weinberg  
 Director, Quality & Certification Division 

**IQNet Partners\*:**

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy  
 CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group USA  
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 IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland  
 NYCE-SIGE Mexico PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia  
 SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia

\* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under [www.iqnet-certification.com](http://www.iqnet-certification.com)

[www.sii.org.il](http://www.sii.org.il)