

# NSAI

## Certificate of Registration of Quality Management System to ISO 13485:2016

The National Standards Authority of Ireland  
A CMDCAS Recognized Registrar certifies that:

**Cliniqa Corporation**  
**495 Enterprise Street**  
**San Marcos, CA 92078**  
**USA**

has been assessed and deemed to comply with the requirements of the above standard in respect of the scope of operations given below:

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**The design, development and manufacture of in-vitro diagnostic controls, calibrators, raw materials, reagents and kits for the diagnosis, management, detection of blood analytes, blood components, cardiac markers, cancer, therapeutic drug monitoring, and drugs of abuse.**

**Additional sites covered under this multi-site certification are listed on the Annex (File No. CM19.3440)**

Approved by:  
Geraldine Larkin  
Chief Executive Officer

Approved by:  
Eoin Banville  
Operations Manager,  
Medical Devices

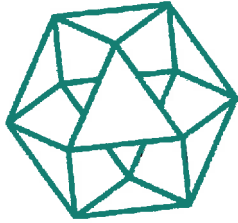
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Registration Number: CM19.3440  
Certification Granted: Aug 13, 2007  
Effective Date: Jul 10, 2018  
Expiry Date: Dec 31, 2018



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# NSAI

**Annex to Certificate Number: CM19.3440**

## **Scope of Registration:**

**The design, development and manufacture of in-vitro diagnostic controls, calibrators, raw materials, reagents and kits for the diagnosis, management, detection of blood analytes, blood components, cardiac markers, cancer, therapeutic drug monitoring, and drugs of abuse.**

### **Activity**

### **Location**

Headquarters, Production

Cliniq Corporation  
495 Enterprise Street  
San Marcos, CA 92078  
USA  
File No.: CM19.3440

Warehouse

Cliniq Corporation  
258 La Moree Road  
San Marcos, CA 92078  
USA  
File No.: CM19.3440/A

**Verified by:**   
**Operations Manager**