

# NSAI

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

The National Standards Authority of Ireland 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:  
Caroline Dore Geraghty  
Director of Medical Devices /  
Head of Notified Body

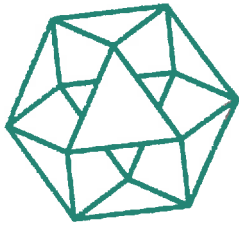
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Registration Number: CM19.3440  
Certification Granted: August 13, 2007  
Effective Date: June 05, 2019  
Expiry Date: June 04, 2022



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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, Administration,  
Production

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

Warehouse

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

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

*Dawn Gast, JGA*