

NSAI

Certificate of Registration of Quality Management System to I.S. EN 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:

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.

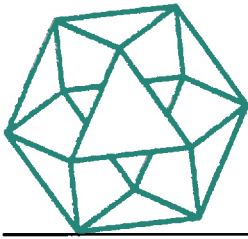
Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.3440)

Approved by:
Geraldine Larkin
Chief Executive Officer

Approved by:
Caroline Dore Geraghty
Director of Medical Devices /
Head of Notified Body

Registration Number: MD19.3440
Certification Granted: July 22, 2009
Effective Date: June 05, 2019
Expiry Date: June 04, 2022





NSAI

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800

Annex to Certificate Number: MD19.3440

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.: MD19.3440

Warehouse

Cliniqa Corporation
258 La Moree Road
San Marcos, CA 92078
USA
File No.: MD19.3440/A

Verified by: *Dawn Gast, DG*
Operations Manager