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

Australia-Therapeutic Goods (Medical Devices) Regulations, 2002,
☒ Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure.
Brazil - RDC ANVISA n. 665/2022 RDC ANVISA n. 551/2021 RDC ANVISA n. 67/2009
Canada - Medical Devices Regulations – Part 1- SOR 98/282
Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act (as applicable)
United States - 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D,
☒ 21 CFR 820 – Quality System Regulation

The National Standards Authority of Ireland is an MDSAP Recognized Auditing Organization and certifies that:

Cliniqa Corporation
495 Enterprise Street
San Marcos, CA 92078
USA
Facility ID: F002805

has been assessed and deemed to comply with the requirements of the above standard and regulations 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. MP19.3440)

Approved by:
Kevin Mullaney
Director of Certification

Certificate Number: MP19.3440 / Rev 1
Certification Granted: 2019/06/05
Effective Date: 2022/06/05
Expiry Date: 2025/06/04

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800
National Standards Authority of Ireland, 20 Trafalgar Square, Nashua, New Hampshire, NH 03063, USA T +1 603 882 4412
All valid certifications are listed on NSAI's website – www.nsaiinc.com The continued validity of this certificate may be verified under "Approved Client Listing

Annex to Certificate Number: MP19.3440 / Rev 1

Scope of Registration:

Proposed scope: 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, Design	Cliniqa Corporation 495 Enterprise Street San Marcos, CA 92078 USA File No.: MP19.3440 Facility ID: F002805
Warehouse	Cliniqa Corporation 258 La Moree Road San Marcos, CA 92078 USA File No.: MP19.3440/A Facility ID: F002805

Verified by:
Director of Certification