

Contract Number WW/MD1-616647

The quality management system of

OnCore de Mexico, S.A de C.V. dba Neo tech Letter of Conformity

20120 Hector Teran Teran Blvd
Tijuana Baja CA 22444 Mexico

Facility identification number : F005355

has been audited against the criteria stated below and found to conform to those criteria for the scope contained in this Letter of Conformity



In Accordance with applicable requirements of MDSAP(ISO 13485:2016)

Brazil:
RDC ANVISA n. 16/2013

Japan:
MHLW Ministerial Ordinance No.169 (2004) as amended by MHLW
Ordinance No. 128 (2014) Articles 4 to 68

United States:
21 CFR 820 / 21 CFR 803 / 21 CFR 806 / 21 CFR 807 – Subparts A to D

For the following activities and devices

Contract manufacture of active, non-implantable, monitoring devices of non-vital physiological parameters, ophthalmologic devices, non-active devices with measuring function, associated electronic components & assemblies for the medical device industry

This Letter of Conformity is valid from
Effective Date: 2021-04-08 until Expiry Date: 2024-04-07
and remains valid subject to satisfactory surveillance audits.
Re-verification audit due before 2024-02-17
Issue 1. Verified since 2021-04-08

Authorised by J Hall
Business Manager

A handwritten signature in black ink that reads 'Jonathan M. Hall'.

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SGS MDSAP 1116

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Certificate US20/819944094.00

The management system of

OnCore de Mexico S.A. de C.V.Dba NEO Tech

Bldv Hector Teran Teran # 20120 Nave 7, Parque Industrial Prologis Mesa
de Otay Tijuana, BC 22444 Mexico

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 28 April 2021 until 28 April 2024
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 17 February 2024

Issue 2. Certified since 18 May 2012

Multiple certificates have been issued for this scope

The main certificate is numbered US20/819944094.00

This is a multi-site certification.

Additional site details are listed on the subsequent page.

Authorised by



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Certificate US20/819944094.00, continued

OnCore de Mexico S.A. de C.V.Dba NEO Tech



ISO 13485:2016 EN ISO 13485:2016

Issue 2

Detailed scope

The contract manufacture and assembly of printed circuit boards, cable and harness assemblies and electromechanical assemblies for medical devices.

Additional facilities

Calle 3 Oriente #18988 Esq. 9 Sur Ciudad Industrial Mesa de Otay , Tijuana, Baja California, 22500, Mexico



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