



Certificate Number US20/819943741

The quality management system of

Electrochemical Oxygen Concepts, Inc.

12500 Network Blvd, Suite 310, San Antonio, TX, 78249, United States

Facility identification number : F004128

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



MDSAP(ISO 13485:2016)

Canada:

Medical Devices Regulations – Part 1 SOR 98/282

United States:

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

For the following activities and devices

Design and manufacture of tissue oxygenation and wound monitoring systems, including sterile hydrophilic dressings, for the use of Continuous Diffusion of Oxygen (CDO) therapy in the treatment and monitoring of wounds for the area of wound care and plastic surgery.

This certificate is valid from

Effective Date: 2021-11-10 until Expiry Date: 2024-09-22

and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 2024-08-27

Issue 3. Certified since 2020-01-10

Authorised by LHenderson
Business Manager

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Page 1 of 1



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