

Certificate US20/819943741

The quality management system of

Electrochemical Oxygen Concepts, Inc., dba EO2 Concepts

12500 Network Blvd, Suite 310, San Antonio, TX, 78249, United States Of America
Facility number: F004128

has been assessed and certified as meeting the requirements of

MDSAP (ISO 13485:2016)

Canada: Medical Devices Regulations – Part 1 SOR 98/282

United States: 21 CFR Part 803 - Medical Device Reporting; 21 CFR Part 806 - Reports of Corrections and Removals;

21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing; 21 CFR Part 820 - Quality System Regulation

For the following activities

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 2022-10-04 until Expiry date 2024-09-22 and remains valid subject to satisfactory surveillance audits.

Issue 4. Certified since 2020-01-10.

Certified activities performed by additional sites listed on subsequent pages.



Authorised by

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SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at www.SGS.com



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