The quality management system of

Electrochemical Oxygen Concepts, Inc.

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

Dun & Bradstreet D-U-N-S identification number: 94-893-8092

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)

Medical Devices Regulations – Part 1 SOR 98/282

<u>United States:</u>
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: 2020-06-22 until Expiry Date: 2023-01-09 and remains valid subject to satisfactory surveillance audits. Re certification audit due before 2021-08-09 Issue 2. Certified since 2020-01-10 Authorised by J Hall Business Manager

Jonathan M. Wall

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