EC Certificate Full Quality Assurance System: Certificate US11/81854

The management system of

Electrochemical Oxygen Concepts, Inc.

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

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Tissue oxygenation system consisting of oxygen generating device (TransCu O2®), sterile wound oxygen delivery cannulas, sterile oxygen extension sets, and sterile hydrophilic dressings (OxySpur™ Oxygen Diffusion Dressings).

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 12 September 2019 until 24 May 2024 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 09 August 2021

Issue 6. Certified since 14 February 2011

Certification is based on reports numbered WW/MW 602557

Authorised by

Jordhan M. Vall

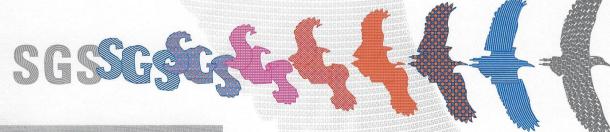
SGS United Kingdom Ltd, Notified Body 0120

202B Worle Parkway, Weston-super-Mare, BS22 6WA UK t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 02 0215

Page 1 of 1





This document is issued by the Company subject to its General Conditions of Certification Services accessible at www.sgs.com/terms, and, conditions.htm.
Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at http://www.sgs.com/en/certified-clients-and-products/certified-client-directory.

Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

