EC Certificate Full Quality Assurance System: Certificate US19/819943608

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, non-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 29 September 2020 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 3. Certified since 14 February 2011
and first certified by SGS Belgium NV since 16 December 2019.

Certification is based on reports numbered WW/MW 602557

Authorised by

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