CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Telesair, Inc.

(FIN F007241)

Main Site: 199 Technology Dr., Suite 110,

Irvine, California, 92618, United States

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

Brazil: RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021, RDC ANVISA n. 67/2009

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)

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68; PMD Act (as applicable)

The management system is applicable to:

The design and development, manufacture, and service of medical respiratory device. Distribution of Oxygen Regulator Set; Oxygen Flowmeter Set; Tubing; and UPS Battery for medical respiratory device.

Certificate Number:
0185100

Revision Level: 00

Initial Certification Date:
2024-08-24

Certification Effective Date:
2024-08-24

Certification Expiry Date:
2027-08-23

Calin Moldovean
President, Business Assurance

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