Certificate US20/819944105

The quality management system of

Sechrist Industries Inc.

4225 East La Palma, Anaheim, CA, 92807, United States Of America

Facility number: F005020

has been assessed and certified as meeting the requirements of

MDSAP (ISO 13485:2016)

Australia: Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System;
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
Japan: MHLW Ministerial Ordinance No.169 (2004) as amended by MHLW Ordinance No. 128 (2014) Articles 4 to 68; PMD Act
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, manufacture, installation, and servicing of Hyperbaric Chambers and Gurneys for oxygen administration to patients, Hyperbaric Electronic Records Organizer for handling of medical device data, and Infant Ventilators, and Gas Mixers for respiratory care and heart bypass oxygenation equipment.

This certificate is valid from Effective date 2022-05-25 until Expiry date 2025-05-14 and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 2020-10-27

Authorised by
Geofrey De Visscher
Head of Notified Body 1639

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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.