



Certificate Number US20/819944105

The quality management system of

Sechrist Industries Inc.

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

Dun & Bradstreet D-U-N-S identification number: 06-208-4215

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)

Australia:
Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure [including design]

Brazil:
RDC ANVISA n. 16/2013 / RDC ANVISA n. 23/2012 / RDC ANVISA n. 67/2009

Canada:
Medical Devices Regulations – Part 1 SOR 98/282

Japan:
MHLW Ministerial Ordinance 169, Article 4 to Article 68 / PMD Act

United States:
21 CFR 820 / 21 CFR 803 / 21 CFR 806 / 21 CFR 807 – Subparts A to D

For the following activities and devices

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: 2020-10-27 until Expiry Date: 2023-10-26 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 2022-05-14

Issue 1. Certified since 2020-10-27

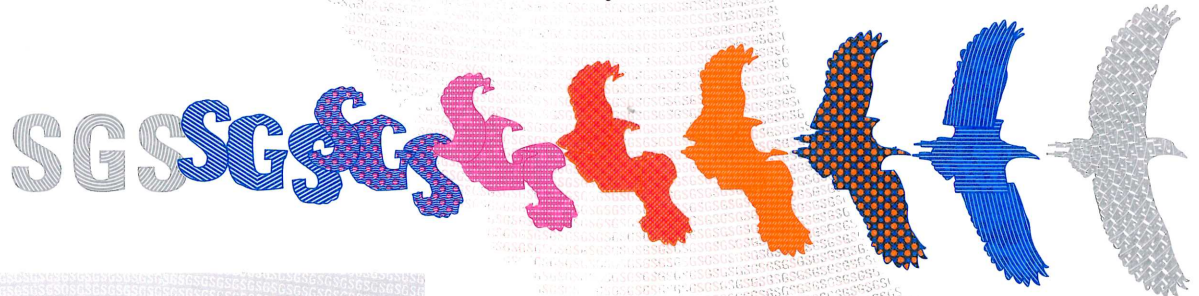
Authorised by J Hall
Business Manager

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