Certificate US20/819943855

The quality management system of

Critical Care Diagnostics, Inc. (C2Dx)

555 E Eliza Street Suite A, Schoolcraft, MI, 49087, United States Of America
Facility number: F004410

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
Canada: Medical Device Regulations SOR/98-282, Part 1
Japan: MHLW Ministerial Ordinance No.169 (2004) as amended by MHLW Ordinance No. 155 (2020);
Japan PMD Act
USA: 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, development, manufacture and distribution of non-sterile intra-compartmental pressure monitor and sterile pre-filled syringes, sterile 18-gauge needle, sterile chamber assembly and sterile indwelling catheter used in intra-compartmental monitoring systems for areas of orthopaedics and emergency medicine.

Design, development, manufacture, distribution, and service of non-sterile localized temperature therapy pump and non-sterile temperature therapy pad used for orthopaedic conditions, skin trauma, and other medical conditions.

This certificate is valid from Effective date 2023-09-06 until Expiry date 2025-12-12 and remains valid subject to satisfactory surveillance audits.

Issue 3. Certified since 2020-03-19

L. Henderson

Authorised by
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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.