

Certificate US20/819943855

The quality management system of

C2Dx, Inc.

SGS

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 Devices Regulations (SOR/98-282) Part 1 - General

Japan: MHLW Ministerial Ordinance No.169 (2004) as amended by MHLW Ministerial Ordinance No. 60 (2021), Japan PMD Act (as applicable)

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.

Design, development, manufacture, and service of thermal scalpel system.

This certificate is valid from Effective date 2025-06-18 until Expiry date 2028-04-22 and remains valid subject to satisfactory surveillance audits.

Issue 4. Certified since 2020-03-19

Certified activities performed by additional sites are listed on subsequent pages.

L. Henderson

Authorised by

Lynn Henderson

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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.



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MDSAP (ISO 13485:2016)

Issue 4

Sites

C2Dx, Inc.
555 E Eliza Street, Suite A, Schoolcraft, MI 49087, United States of America
Facility number: F004410

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.

Design, Development and distribution of Thermal Scalpel system.

C2Dx, Inc.
8400 Wolf Lake Drive, Suite 109, Bartlett, TN 38133, United States of America
Facility number: F008100

Manufacture and service of thermal scalpel system.



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