

Certificate US20/819943909

The management system of

## C2Dx, Inc.

555 E Eliza Street, Suite A, Schoolcraft, MI 49087, United States of America

has been assessed and certified as meeting the requirements of

**ISO 13485:2016**

**EN ISO 13485:2016**

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 22 April 2025 until 22 April 2028 and remains valid subject to satisfactory surveillance audits.

Issue 5. Certified since 22 April 2020

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

*L. Moran*

Authorised by

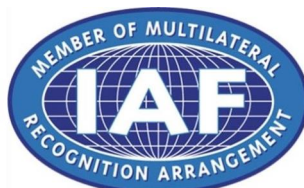
Liz Moran

Business Manager

SGS United Kingdom Ltd

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**ISO 13485:2016**  
**EN ISO 13485:2016**

Issue 5

**Sites**

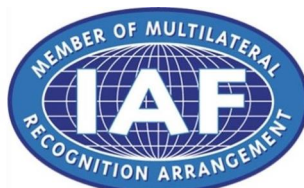
C2Dx, Inc.  
555 E Eliza Street, Suite A, Schoolcraft, MI 49087, United States of America

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  
Manufacture and service of thermal scalpel system.



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