

Certificate US20/819943909

The management system of

Critical Care Diagnostics, Inc. (C2Dx)

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.

This certificate is valid from 06 September 2023 until 13 December 2025 and remains valid subject to satisfactory surveillance audits.

Issue 4. Certified since 22 April 2020

Authorised by
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Global Head - Certification Services

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