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CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Mercury Medical Enterprises, LLC

(FIN #F006764)

Main Site: 11300 49th Street North

Clearwater, Florida, 33762, United States

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

Brazil: RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021, RDC ANVISA n. 67/2009

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

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

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

The management system is applicable to:

The design, manufacture, and distribution of breathing circuits, airway pressure devices, CO2 detectors, airway pressure monitors, patient position supports, anesthetic gas masks, oxygen masks, nebulizers, and accessories for anesthesia, respiratory, and critical care environments, specifically, EMS, physicians offices, clinics, and hospitals.

Organization was certified by another Certification Body before 08/10/2023

Certificate Number:
0151184

Revision Level: 05

Initial Certification Date:
2020-01-24

Certification Effective Date:
2026-11-03

Certification Expiry Date:
2028-01-23

ISO 13485:2016 CERTIFICATION TM
intertek

MDSAP
Medical Device Single Audit Program

Mark Thomas
Executive Vice President
Assurance, Sustainability, AgriWorld & Food
Intertek Testing Services NA, Inc.
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In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request. Validity of this certificate may be verified at http://www.intertek.com/business-assurance/certificate-validation/