EC CERTIFICATION

QUALITY MANAGEMENT SYSTEM CERTIFICATE

EU Regulation 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation restricted to the aspects relating to the conformity of the devices with metrological requirements - has been carried out following the requirements of Regulation (EU) 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

Certificate Number:
28620161639

Revision:
00

Initial Certification Date:
5 December 2023

Date of Certification Decision:
5 December 2023

Certificate Issue Date:
5 December 2023

Certificate Expiry Date:
23 January 2028

Mercury Medical

11300 49th Street, North Clearwater, Florida, 33762, United States

Manufacturer SRN: US-MF-000002015

Authorised Representative Name
Emergo Europe B.V.
Westervoortsedijk, 60 6827 AT Arnhem

Scope:

Metrology aspects of devices as detailed in attached product list.

Dawn Chivers
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

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 organisation 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

PRODUCT LIST FOR CERTIFICATE

See attached Product List

EXAMINATION AND TESTS PERFORMED

Last Audit report reference	Transfer Review - ACTY-2023-110034

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

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CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES

Certificate No:	28620161639
Date:	5 December 2023
Handled by:	Carmina Henningsson
E-mail:	IMNB@intertek.com

Mercury Medical
Attn: Peter Traina
11300 49th Street,
North Clearwater, Florida, 33762,
United States

Purpose

Assessment to issue a new certificate according to the Medical Device Regulation 2017/745, Annex IX.
Expiry date on MDR certificate is set to be aligned with client´s audit cycle for ISO 13485:2016 certificate.

Activity

Audit Type	Location	Auditor Name	Audit Date
Transfer Review	Desktop	Mikael Hagelin	28-29 September

Scope of assessment

Metrology aspects of devices as detailed in attached product list, Class Im

Result

No minor/major non conformities were noted during the transfer audit.

Certificate Type

Quality Management Certificate

Certificate Valid from

5 December 2023

Conclusions/Decisions

Referring to the above, a Certificate of Conformance with the Device Regulation 2017/745, Annex IX will be issued. The Certificate is valid for products specified in the “MDR – Product List”.

Follow-up assessments

Follow-up assessments are going to be performed once per year.

Appeals

Any appeal against this decision will be processed by an appeals panel as Intertek. The appeal shall be submitted to Intertek Medical Notified Body AB, PO-Box 1103, SE-164 22 Kista, Sweden (imnb@intertek.com).

Others

Any complaints, from customers and others, and corrective actions concerning your certified quality system shall be documented and retained. Upon request Intertek Medical Notified Body AB has the right to review this documentation.

Intertek Medical Notified Body AB
Notified Body MDR

Dawn Chivers
Certification Authority (Audit)

PRODUCT LIST FOR CERTIFICATE

Issued to: Mercury Enterprises, Inc.

Certificate number: 28620161639

Certificate valid from: 2023-12-05

Product List Issue Date:
05 December 2023

Product	Classification and EMDN	Intended use[1]	Date Added
Class I devices with a measuring function			
Basic UDI-DI: 0641043MAMT			
10-55350 - Disposable Manometer	Class I(m) R03020201		2023-12-05
10-55351 - Disposable Manometer	Class I(m) R03020201		2023-12-05
10-55352 - Disposable Manometer	Class I(m) R03020201		2023-12-05
10-55353 - Disposable Manometer	Class I(m) R03020201		2023-12-05
10-55354 - Disposable Manometer	Class I(m) R03020201		2023-12-05
10-55356 - Disposable Manometer	Class I(m) R03020201		2023-12-05
10-55357 - Disposable Manometer	Class I(m) R03020201		2023-12-05
10-55358 - Disposable Manometer	Class I(m) R03020201		2023-12-05
10-55359 - Disposable Manometer	Class I(m) R03020201		2023-12-05
10-55364 - Disposable Manometer	Class I(m) R03020201		2023-12-05
10-55365 - Litesaver Manometer	Class I(m) R03020201		2023-12-05
10-55366 - LiteSaver Manometer	Class I(m) R03020201		2023-12-05
10-55367 - LiteSaver Manometer	Class I(m) R03020201		2023-12-05
10-55377 - Disposable Manometer	Class I(m) R03020201		2023-12-05
10-55378 - Disposable Manometer	Class I(m) R03020201		2023-12-05
10-55379 - Disposable Manometer	Class I(m) R03020201		2023-12-05
10-55381 - Disposable Manometer	Class I(m) R03020201		2023-12-05

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
10-55382 - Disposable Manometer	Class I(m) R03020201		2023-12-05

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[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Certificate number: 28620161639
Product list issue date: 05 December 2023