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 reusability 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:
28620170242

Revision:
00

Initial Certification Date:
19 March 2024

Date of Certification Decision:
19 March 2024

Certificate Issue Date:
19 March 2024

Certificate Expiry Date:
18 December 2028

M Dialysis AB

Hammarby Fabriksväg 43 120 30 Stockholm Sweden

Manufacturer SRN: SE-MF-000017466

Scope:

Reusability aspects of devices as detailed in attached product list.

Mikael Hagelin
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.

PRODUCT LIST FOR CERTIFICATE

See attached Product List

EXAMINATION AND TESTS PERFORMED

Last Audit report reference	**Stage 1 audit ACTY-2022-607917**
	Stage 2 audit ACTY-2022-607919

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES

Certificate Number:
28620170242

Revision:
00

Initial Certification Date:
19 March 2024

Date of Certification Decision:
19 March 2024

Certificate Issue Date:
19 March 2024

Certificate Expiry Date:
18 December 2028

Mikael Hagelin
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.

MDR – Decision Report

Certificate No: 28620170242
Date: 19 March 2024
Handled by: Caroline Åman
E-mail: IMNB@intertek.com

M Dialysis AB
Attn: Charlotte Woschnagg
Hammarby Fabriksväg 43
SE-120 30 Stockholm
Sweden

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
Stage 1 ACTY-2022-607917	Stockholm	Gabriel Johansson	7 – 8 Sep 2023
Stage 2 ACTY-2022-607919	Stockholm	Gabriel Johansson	13 – 15 Nov 2023

Scope of assessment

Reusability aspects of devices as detailed in attached product list.
Class I(r)

Result

1 minor non conformitiy were noted during the audit. Presented corrective action plans have been examined and approved by us.

Certificate Type

EU Quality Assurance Certificate

Certificate Valid from

19 March 2024

Conclusions/Decisions

Referring to the above, a Certificate of Conformance with the Medical 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.

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 has the right to review this documentation.

Intertek Medical Notified Body AB
Notified Body MDR

Mikael Hagelin
Certification Authority (Audit)

PRODUCT LIST FOR CERTIFICATE

Issued to: M Dialysis AB

Certificate number: 28620170242

Certificate valid from: 2024-03-19

Product List Issue Date:
19 March 2024

Product	Classification and EMDN	Intended use[1]	Date Added
Class I reusable surgical instruments			
Basic UDI-DI: 7332699_F0070_330_QW			
P000055 - Tunnelating needle	Class I(r) A010199		2024-03-19
P000056 - Forceps	Class I(r) L23		2024-03-19

Mikael Hagelin
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.

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