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EC CERTIFICATION

FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0413 marking on those products listed below.

Organization:

M Dialysis AB

Main Site: Hammarby Fabriksväg 43, 120 30 Stockholm, Sweden

Product Category:

- Microdialysis Catheters
- Introducers for microdialysis catheters
- Sterile perfusion fluid for microdialysis
- Microdialysis pumps for clinical use
- Syringes for use with microdialysis pumps
- Microdialysis system

For further identification of the products covered, see the MDD product list/product schedule.

Certificate Number:
41319041-03

Initial Certification Date:
12 December 2011

Certificate Valid from:
03 April 2020

Certificate Expiry Date:
26 May 2024

SWEDAC ACKREDITERING
Accred. no. 1003
Certification of Management Systems
ISO/IEC 17021-1

Peter Nermander
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

03 April 2020
Signed Date

Intertek Semko AB
Box 1103, SE-164 22 Kista, Sweden
Telephone +46 8 750 00 00
medtechsweden@intertek.com

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

Intertek Semko AB is a Notified Body according to Directive 93/42/EEC on medical devices, with identification number 0413.

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MDD – Product List

Products included in the certificate no: 41319041-03
Issued to: **M Dialysis AB**
Hammarby Fabriksväg 43
120 30 Stockholm
Sweden

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Microdialysis Catheters					
	8010226 61 Microdialysis Catheter	IIa	Yes	45469	12 Dec 2011
	8010292 62 Gastrointestinal Microdialysis Catheter	IIa	Yes	45469	12 Dec 2011
	8010509 63 Microdialysis Catheter 60/10	IIa	Yes	45469	12 Dec 2011
	8010514 63 Microdialysis Catheter 40/30	IIa	Yes	45469	12 Dec 2011
	8010650 66 Linear Catheter 30mm 20kD	IIa	Yes	45469	12 Dec 2011
	8010670 66 Linear Catheter 10mm 20 kD	IIa	Yes	45469	12 Dec 2011
	8010651 66 High Cut Off Linear Catheter 30mm 100 kD	IIa	Yes	45469	12 Dec 2011
	8010671 66 High Cut Off Linear Catheter 10mm 100 kD	IIa	Yes	45469	12 Dec 2011
	8050090 67 IV MD Catheter 46/10	IIa	Yes	45469	6 Nov 2015
	8050091 67 IV MD Catheter 46/20	IIa	Yes	45469	6 Nov 2015
	8050092 67 IV MD Catheter 46/30	IIa	Yes	45469	6 Nov 2015
	8050093 67 IV MD Catheter 130/10	IIa	Yes	45469	6 Nov 2015
	8050191 61 High Cut Off Microdialysis Catheter	IIa	Yes	45469	19 Dec 2019

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MDD – Product List

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Introducers for Microdialysis Catheters					
	8010343 Splitable Introducer SI-2	IIa	Yes	45469	12 Dec 2011
Sterile Perfusion Fluid for Microdialysis					
	P000034 Perfusion Fluid T1	IIa	Yes	45467	12 Dec 2011
	P000151 Perfusion Fluid CNS	IIa	Yes	45467	12 Dec 2011
	CNS DEXTRAN	IIa	Yes	45467	21 June 2018
Microdialysis pumps for clinical use					
	P000003 106 Microdialysis Pump	IIa	No	45470	12 Dec 2011
	P000127 107 Microdialysis Pump	IIa	No	45470	12 Dec 2011
Syringes for use with Microdialysis Pumps					
	8010191 106 Syringe	IIa	Yes	45467	12 Dec 2011
Microdialysis system					
	MD System1.0	IIa	No		30 Mar 2020

Sign Date: 03 April 2020

Intertek Semko AB
Notified Body MDD

Peter Nermander
Certification Authority MDD

This product list is only valid together with the referenced, valid EC certificate.

The GMDN codes are assigned by the manufacturer and are only provided for convenience.

Intertek Semko AB is a Notified Body according to the Directive 93/42/EEC on medical devices, with identification number 0413.

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MDD – Decision Report

Certificate No: 41319041-03
Date: 3 April 2020
Handled by: Caroline Åman
E-mail: medtechsweden@intertek.com

M Dialysis AB
Attn: Tu Du
Hammarby Fabriksväg 43
120 30 Stockholm
Sweden

Purpose	Assessment to issue a new EC Certificate due to change of scope. The category - *Microdialysis system* has been added. Decision was made according to the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II.
Scope of assessment	- Microdialysis Catheters - Introducers for microdialysis catheters - Sterile perfusion fluid for microdialysis - Microdialysis pumps for clinical use - Syringes for use with microdialysis pumps - Microdialysis system Class IIa
Result	*MD System1.0* have been added to the product list (refer to separate Product Decision dated 2020-03-30), and the scope of the certificate can be updated.
Certificate Valid from	3 April 2020
Conclusions/Decisions	Referring to the above a Certificate of Conformance with the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II will be issued. The Certificate is valid for products specified in the "MDD – Product List".
Follow-up assessments	Follow-up assessments are going to be performed once a year.
Appeals	Any appeal against this decision will be processed by an appeals panel as Intertek. The appeal shall be submitted to Intertek Semko 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 Semko has the right to review this documentation.

Intertek Semko AB
Notified Body MDD

Peter Nermander
Certification Authority MDD

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MDD – Product Decision

Certificate No: 41319041
Date: 30 March 2020
Handled by: Lieselotte Hanisch
E-mail: medtechsweden@intertek.com

M Dialysis AB
Att: Olof Nord
Hammarby Fabriksväg 43
120 30 Stockholm

Purpose

Assessment of the application dated 15 January 2019 to add new product to be included in your certified quality system according to LVFS 2003:11, Annex II (Swedish implementation of MDD 93/42/EEC).

Products concerned

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)
Microdialysis system	MD System 1.0	IIa	N	-

Conclusions/Decisions

The TD review was accepted 13 March 2020, the scope can be expanded with a new product group, Class IIa, MD1301. The product MD System 1.0 can be added to the product group, however a new Product category needs to be added to the certificate: Microdialysis system.

Application of the CE-mark is permitted when the company's own procedures for CE-marking are fulfilled.

Appeals

Any appeal against this decision will be processed by an appeals panel at Intertek. The appeal shall be submitted to Intertek Semko AB, PO-Box 1103, SE-164 22 Kista, Sweden.

Intertek Semko AB
Notified Body MDD

Peter Nermander
Certification Authority MDD