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EC CERTIFICATION

FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC on Medical Devices, Annex II

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 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:3

- Brain Microdialysis Catheter

For further identification of the products covered, see the MDD Appendix.

*For CE marking the class class III devices covered by this certificate an EC Design Examination certificate according to Annex II section 4 is also required.

Certificate Number:
41319031-02

Initial Certification Date:
12 December 2011

Certificate Valid from:
2 February 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

2 February 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: 41319031-02
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
Brain Microdialysis Catheter					
	70 Brain Microdialysis Catheter (60/10) REF: P000049	III	Yes	45469	Dec 12, 2011
	70 Brain Microdialysis Catheter (100/10) REF: P000050	III	Yes	45469	Dec 12, 2011
	70 Brain Microdialysis Catheter (90/20) REF: P000051	III	Yes	45469	Dec 12, 2011
	70 Brain Microdialysis Catheter (80/30) REF: P000052	III	Yes	45469	Dec 12, 2011
	70 Brain Microdialysis Catheter (60/20) REF: P000080	III	Yes	45469	Dec 12, 2011
	70 Brain Microdialysis Catheter (60/30) REF: P000081	III	Yes	45469	Dec 12, 2011
	70 Microdialysis Bolt Catheter (130/10) REF: P000131	III	Yes	45469	Dec 12, 2011
	71 High Cut-Off Brain Microdialysis Catheter (60/10) REF: 8010320	III	Yes	45469	Dec 12, 2011

Intertek Semko AB
Torshamnsgatan 43, Box 1103, SE-164 22 Kista, Sweden
Telephone +46 8 750 00 00, Fax +46 8 750 60 30, www.sweden.intertek-etlsemko.com
Registered in Sweden: No SE556024059901, Registered office: As address

	71 High Cut-Off Brain Microdialysis Catheter (60/20) REF: 8010331	III	Yes	45469	Dec 12, 2011
	71 High Cut-Off Brain Microdialysis Catheter (60/30) REF: 8010337	III	Yes	45469	Dec 12, 2011
	71 High Cut-Off Brain Microdialysis Catheter (130/10) REF: 8010954	III	Yes	45469	Jan 30, 2020

Signed date: 2 February 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.

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Registered in Sweden: No SE556024059901, Registered office: As address

MDD – Decision Report

Certificate No: 41319031-02
Date: 2 February 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 certificate due to five year extension according to the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II.
Activity	Certification audit was performed 17 September in Stockholm by Grzegorz Pawlowski. The Design Examination was performed by Vincenzo Tilotta at Intertek's office and completed 30 January 2020.
Scope of assessment	- Brain Microdialysis CatheterClass IIa
Result	0 non conformities were noted during the audit. No open Non-conformities from Design Examination remain.
Certificate Valid from	2 February 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

MDD – Product Decision

Certificate No: 41319031-01
Date: Januari 31, 2020
Handled by: Caroline Åman
E-mail: medtechsweden@intertek.com

M Dialysis AB
Attn: Tu Du
Box 5049
SE-121 05 Stockholm
Sweden

Purpose

Assessment of the notification dated June 26, 2019 to add new products to your quality system certified 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)
Brain Microdialysis Catheter	71 High Cut-off Microdialysis Bolt Catheter, Ref. 8010954	III	Yes	45469

Conclusions/Decisions

The device was included in the Design Examination for renewal of Design Examination certificate No. 41319021, report dated 2020-01-30, and can be added to the scope.

Follow-up assessments

At the next audit your auditor may follow-up on the implementation of the new products in the Quality system.

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