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EC CERTIFICATION

EC DESIGN EXAMINATION CERTIFICATE

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

We hereby declare that a design examination has been carried out on the devices(s) listed hereafter following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex II section 4 of the Directive 93/42/EEC on medical devices. We certify that the design of the device(s) listed hereafter conforms with the relevant provisions of Annex II section 4 of the aforementioned legislation, and the result entitles the organization to use the CE 0413 marking on those products*.

Organization:

M Dialysis AB

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

Product Category:

- 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 certificate according to Annex II section 3 is also required.

Certificate Number:
41319021-02

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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Appendix to EC design examination Certificate no 41319021-02

Version:	1
Issued to:	**M Dialysis AB** Hammarby Fabriksväg 43 120 30 Stockholm Sweden
Review report:	Dated: 30 January 2020

Product	Model/ REF	GMDN
70 Brain Microdialysis Catheter (60/10 shaft/membrane length in mm)	P000049	45469
70 Brain Microdialysis Catheter (100/10 shaft/membrane length in mm)	P000050	45469
70 Brain Microdialysis Catheter (90/20 shaft/membrane length in mm)	P000051	45469
70 Brain Microdialysis Catheter (80/30 shaft/membrane length in mm)	P000052	45469
70 Brain Microdialysis Catheter (60/20 shaft/membrane length in mm)	P000080	45469
70 Brain Microdialysis Catheter (60/30 shaft/membrane length in mm)	P000081	45469
70 Microdialysis Bolt Catheter (130/10 shaft/membrane length in mm)	P000131	45469
71 High Cut-Off Brain Microdialysis Catheter (60/10 shaft/membrane length in mm)	8010320	45469
71 High Cut-Off Brain Microdialysis Catheter (60/20 shaft/membrane length in mm)	8010331	45469
71 High Cut-Off Brain Microdialysis Catheter (60/30 shaft/membrane length in mm)	8010337	45469
71 High Cut-Off Brain Microdialysis Catheter (130/10 shaft/membrane length in mm)	8010954	45469

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

Appendix to EC design examination Certificate no 41319021-02

Sterilization method: β-Radiation

Description of Intended use:
Implantation into human brain tissue to enable microdialysis of the extracellular fluid.

Signed date: 2 February 2020

Intertek Semko AB
Notified Body MDD

Peter Nermander
Certification Authority MDD

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

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: 41319021-02
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	The Design Examination was performed by Vincenzo Tilotta at Intertek's office and completed 30 January 2020.
Scope of assessment	- Brain Microdialysis Catheter, Class III
Result	No open Non-conformities 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 Appendix.
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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DD - Review Decision

Certificate No: 41319021
Date: 30 Jan 2020
Handled by: Vincenzo Tilotta
E-mail: medtechsweden@intertek.com

M Dialysis AB
Hammarby Fabriksväg 43,
SE-120 30, Stockholm, Sweden

Activity	Review of the Design Dossier for Design Examination Certificate renewal according to MDD 93/42 EEC (Swedish implementation LVFS 2003:11) as amended by 2007/47/EC (Swedish implementation LVFS 2009:18), Annex II section 4.
Review based on	European Guidance documents (MEDDEVs, NB-Meds and NBOG BPGs) and Intertek's procedures.
Reviewed by	Vincenzo Tilotta (Lead Assessor and clinical), Lee Simpson (Sterilisation).
Review dates	4 Dec 2019, 30 Jan 2020.
Location	Kista, Sweden
Product	Sterile Brain Microdialysis Catheters, Class III (see the following pages for a complete list).
Conclusion	The Design Dossier for the above-mentioned products, including corrective actions, has been reviewed and found to contain the information prescribed in the regulations. The information has been found to be plausible and credible. The Design Dossier is therefore accepted and an EC Design Examination (renewal) certificate can be issued.

Intertek Semko AB
Notified Body MDD

Peter Nermander
Certification Authority MDD

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DD - Review Decision

Product	Model / REF
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