

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:

FHC, Inc

Main Site: 1201 Main Street, Bowdoin, Maine 04287, USA

Product Category:

- microTargeting electrodes
- microTargeting insertion tubes

For further identification of the products covered, see the Appendix to this certificate.

*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:

41318570-03

Initial Certification Date:

24 March 2010

Certificate Valid from:

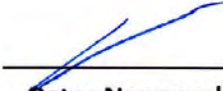
27 May 2020

Certificate Expiry Date:

26 May 2024



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


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

27 May 2020

Signed Date

Intertek Semko AB
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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.



Version:	6
Issued to:	FHC, Inc 1201 Main Street Bowdoin, ME 04287 USA
Review report:	Dated 27 May 2020

Product category/names and key to catalog number	Product catalog number	Sterile
microTargeting Electrodes FHC distributed		
Array Electrde Frme NSterile	22630R	No
Array Elctrde Frame NSterile	22635L	No
Non Sterile Frame Array D.ZAP Electrode	22635Z	No
Array Electrode/Sterile 5pk	22670R	Yes
Array DZAP Leadpoint/Sterile	22675L	Yes
Array DZAP/Sterile 5pk	22675Z	Yes
Non Sterile Frame Single Electrode	34620R	No
Single Electrode Frame	34625L	No
Single Electrode Frame DZap	34625Z	No
Single Electrode Sterile/5p	34680R	Yes
Single DZap Leadpoint	34685L	Yes
Single DZap / Sterile 5pk	34685Z	Yes
Platform Electrode Frame	44930R	No
Platform Elctrde Frme DZap	44935L	No
Platform Elctrde Frme DZap	44935Z	No
Platform Array Sterile/5pk	44970R	Yes
Platform Array Dzap Leadpoint	44975L	Yes
Platform Array Dzap Sterile	44975Z	Yes
Nexframe / Array Sterile/ 5pk	5000R	Yes
Nexframe / DZap Leadpoint / Array Sterile/ 5pk	5005L	Yes
Nexframe / DZap Array Sterile/ 5pk	5005Z	Yes
Nexframe Electrode	5030R	No
Nexframe Electrode DZap	5035L	No
Nexframe Electrode DZap	5035Z	No
Nexframe / Array Sterile / 5pk	5700R	Yes
Nexframe / DZap Leadpoint STar Drive Sterile/ 5pk	5705L	Yes
Nexframe / DZap/ STar Drive Sterile/ 5pk	5705Z	Yes
Nexframe Electrode	5730R	No
Nexframe Electrode DZap	5735L	No
Nexframe Electrode DZap	5735Z	No
Box of 5mT Tungs. Electr.ARDB1	MER-5000T	Yes

Product category/names and key to catalog number	Product catalog number	Sterile
<p>microTargeting Electrodes FHC distributed</p> <p>1: electrode type B: backloaded D: differential F: frontloaded S: shielded</p> <p>2: material and insulation P: platinum/iridium (80/20) with glass or EpoxyLite insulation S: stainless steel with EpoxyLite insulation W: tungsten with EpoxyLite insulation</p> <p>3: impedance A: 500 Kohms (+/- 30%) B: 1.0 Megohms (+/-20%) C: 5.0 Megohms (+/-20%) D: 10 Megohms (+/-20%) L: 1.0 Megohms measured on systems measuring 220Hz X: Specify between 0.1 and 10 Megohms Z: 1.0 Megohms measured on systems measuring 1 KHz</p> <p>4: sterility N: nonsterile P: presterile</p> <p>mTB Electrode length: 100-300mm Exposure: 2-50mm</p> <p>mTD Electrode length: 100-293mm Differential length: 1-50mm Protective tube length: 100-300mm</p> <p>mTF Electrode length: 100-300mm Reach: 90mm-electrode length less 10mm</p> <p>mTS Electrode length: 100-295mm Reach: 1-50mm Protective tube length: 100-300mm Range of motion: 2-75mm</p> <p>x): customer specification (y): customer specification Variations in length, exposure, reach and range of motion</p>	<p>mT1234(x)(y) See key below</p>	<p>See key below</p>

Product category/names and key to catalog number	Product catalog number	Sterile
mT Array Electrodes 6x Non Sterile	22335Z (alternative catalog number for MTDWZN(SP)(AR1), see above)	No
mT Array Electrodes 5x Sterile	22375Z (alternative catalog number for MTDWZP(SP)(AR1), see above)	Yes
mT Array Frame Platinum 6X Non Sterile	25335Z (alternative catalog number for MTDPZN(PA)(AR4), see above)	No
mT Array Frame Platinum 5X Sterile	25375Z (alternative catalog number for MTDPZP(PA)(AR4), see above)	Yes
mT Frame Single Tungsten 6X Non Sterile	34325Z (alternative catalog number for MTDWZB(BP)(BP8), see above)	No
mT Frame Single Tungsten 5X Sterile	34385Z (alternative catalog number for MTDWZP(BP)(BP8), see above)	Yes
mT Single Frame Platinum 6x Non Sterile	35325Z (alternative catalog number for MTDPZN(EP)(BP8), see above)	No
mT Single Frame Platinum 5X Sterile	35385Z (alternative catalog number for MTDPZP(EP)(BP8), see above)	Yes
mT Platform Electrode Tungsten 6X Non Sterile	44335Z (alternative catalog number for MTDWZN(SP)(MP4), see above)	No
mT Platform Electrode Tungsten 5x Sterile	44375Z (alternative catalog number for MTDWZP(SP)(MP4), see above)	Yes
mT Platform Electrode Platinum 6X Non Sterile	45335Z (alternative catalog number for MTDPZN(PA)(MP4), see above)	No
mT Platform Electrode Platinum 5X Sterile	45335Z (alternative catalog number for MTDPZN(PA)(MP4), see above)	Yes

Product category/names and key to catalog number	Product catalog number	Sterile number
microTargeting Electrodes		
Medtronic distributed		
Box of 5 array electrodes	22670	Yes
Box of 5 single electrodes	34680	Yes
Non Sterile Diff mT electrode	FC1002	No
Non Sterile Diff. mT electrod	FC1003	No
Sterile DZAP Array Insertion Electrode 5pk	FC2001	Yes
Sterile DZAP Single Insertion Electrode 5pk	FC2002	Yes
Sterile DZAP Single & Array Insertion Electrode 5pk	FC2003	Yes
Sterile DZAP Single & Array Insertion Electrode 5pk	FC2004	Yes
Box of 5 Pt Nexframe electrode	FC5000	Yes
Insertion and Protective Tubes		
FHC distributed		
Insertion tube	66-IT-x	See key
Protective tubes	66-PT-x	See key
Array Tube Kit for Nexframe	MER-6000	No
Insertion tube	70-IT-x	See key
Insertion tube and Protective tube variations (represented by "x")	Length: 15-300mm Inside diameter: 0.3-1.8mm Outside diameter: 0.5-2.0mm Collar size: 1-5mm diameter Collar type: with or without screw "P": indicates presterile	
Insertion and Protective Tubes		
Medtronic distributed		
Single Electrode Insertion Tube Set for microTargeting Drive or microTargeting STar Drive	FC1011	No
Array Electrode Insertion tube w/stylette, frame	FC1012	No
Array Electrode Insertion Tube Set for microTargeting Drive	FC1018	Yes
Lead Insertion Tube w/ Stylet, Sterile	FC1019	Yes
Single Electrode Insertion Tube Set 5x 20mm Above Target	FC1036	Yes
Array Lead Insert Tubes w/Styl	FC7140LI	Yes
STar Array Electrode Insertion Tube with Stylet 5x	FC8009	Yes
STar Array Electrode Insertion Tube w/ Stylet 5x	FC9001	Yes
Lead Insertion Tube with Stylet 5x pk	FC9002	Yes
STar Single Electrode Insertion Tube 5x for use with Nexframe and STar Drive	FC9003	Yes

Sterilization method:

The MicroTargeting Electrodes and Insertion Tubes are supplied sterile or non-sterile. Products supplied sterile are sterilised using ethylene oxide gas. For the products intended to be sterilised by the user the recommended method is steam sterilisation.

Description of intended use:


The microTargeting Electrodes are intended to be used in intra-operative recording of neuronal activity or stimulation of neural elements in the brain or nervous system during functional neurosurgery. The microTargeting Insertion Tubes are intended to guide microelectrodes, stimulation electrodes or other instruments in the brain or nervous system. The two components may be used separately or together.

Version history

Version	Changes	Date
1	First version	24 Mar. 2010
2	A number of the electrodes and tubes on the list that was FHC distributed will now also be distributed by Medtronic. New article numbers have been added to denote the different distributor (FC 2001 - FC2004, FC1036, FC8011, FC9001 - FC9003, FC8009). This is the only change.	7 Nov. 2011
3	Deleted products MER-3000T, MER-4015T, MER-4020T, 70-IT(xxxx)	30 Jan. 2015
4	Deleted products 70-PT(xxxx), 70-CN-ET, FC8011. The Annex has been updated according to client's request. The product FC5000 has change from no to yes sterile. There has been some small changes in names and key to catalog number. GMDN-codes have been added to the product list. This was provided by manufacture on Notified Body request	23 Sep. 2015
5	FC1011, FC1012, FC1018, FC1036 have been moved from product category micro Targeting Electrodes Medtronic distributed, according to client's request. Keri Seitz works no longer at FHC and is replaced with Fred Haer.	8 Oct. 2015
6	Design Examination renewal, updated based on results from Design Examination	xx May 2020

Valid Date: 27 May 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.

Certificate No: 41318570-03
Date: 27 May 2020
Handled by: Caroline Åman
E-mail: medtechsweden@intertek.com

FHC, Inc.
Attn: Kelly Moeykens
1201 Main Street
Bowdoin, ME 04287
USA

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 David Ben Williams at Intertek's office and completed 27 May 2020.

Scope of assessment - microTargeting electrodes
- microTargeting insertion tubes
Class III

Result No open Non-conformities remain.

Certificate Valid from 27 May 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. A few clerical corrections have been made to align the Appendix with the performed Design Examination.

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