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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:

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 MDD product list/product schedule.

*For placing the class III devices covered by this certificate on the market, an EC design-examination certificate according to MDD Annex II (4) is required.

Certificate Number:
41318560-03

Initial Certification Date:
24 March 2010

Certificate Valid from:
27 May 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

27 May 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.

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organisation maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request

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MDD – Product List

Products included in the Certificate No: 41318560-03
Issued to: **FHC, Inc.**
1201 Main Street
Bowdoin, Maine 04287
USA

Product category/ name and key to catalog number	Product catalog number	Class	Sterile	GMDN code (not mandatory)	Date added
microTargeting Electrodes FHC distributed					
Array Electrode Frame NSterile	22630R	III	No	32556	Mar 24, 2010
Array Electrode Frame NSterile	22635L	III	No	32556	Mar 24, 2010
Non Sterile Frame Array D.ZAP Electrode	22635Z	III	No	32556	Mar 24, 2010
Array Electrode/Sterile 5pk	22670R	III	Yes	32556	Mar 24, 2010
Array DZAP Leadpoint/Sterile	22675L	III	Yes	32556	Mar 24, 2010
Array DZAP/Sterile 5pk	22675Z	III	Yes	32556	Mar 24, 2010
Non Sterile Frame Single Electrode	34620R	III	No	32556	Mar 24, 2010
Single Electrode Frame DZap	34625L	III	No	32556	Mar 24, 2010
Single Electrode Frame DZap	34625Z	III	No	32556	Mar 24, 2010
Single Electrode Sterile/5pk	34680R	III	Yes	32556	Mar 24, 2010
Single DZap Leadpoint/	34685L	III	Yes	32556	Mar 24, 2010
Single DZap / Sterile 5pk	34685Z	III	Yes	32556	Mar 24, 2010
Platform Electrode Frame	44930R	III	No	32556	Mar 24, 2010
Platform Electrode Frme DZap	44935L	III	No	32556	Mar 24, 2010
Platform Electrode Frme DZap	44935Z	III	No	32556	Mar 24, 2010
Platform Array Sterile/5pk	44970R	III	Yes	32556	Mar 24, 2010
Platform Array Dzap Leadpoint	44975L	III	Yes	32556	Mar 24, 2010
Platform Array Dzap Sterile	44975Z	III	Yes	32556	Mar 24, 2010
Nexframe / Array Sterile/ 5pk	5000R	III	Yes	32556	Mar 24, 2010
Nexframe / DZap Leadpoint / Array Sterile/ 5pk	5005L	III	Yes	32556	Mar 24, 2010
Nexframe / DZap Array Sterile/ 5pk	5005Z	III	Yes	32556	Mar 24, 2010

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MDD – Product List

Product category/ name and key to catalog number	Product catalog number	Class	Sterile	GMDN code (not mandatory)	Date added
Nexframe Electrode	5030R	III	No	32556	Mar 24, 2010
Nexframe Electrode DZap	5035L	III	No	32556	Mar 24, 2010
Nexframe Electrode DZap	5035Z	III	No	32556	Mar 24, 2010
Nexframe / Array Sterile / 5pk	5700R	III	Yes	32556	Mar 24, 2010
Nexframe / DZap Leadpoint STar Drive Sterile/ 5pk	5705L	III	Yes	32556	Mar 24, 2010
Nexframe / DZap/ STar Drive Sterile/ 5pk	5705Z	III	Yes	32556	Mar 24, 2010
Nexframe Electrode	5730R	III	No	32556	Mar 24, 2010
Nexframe Electrode DZap	5735L	III	No	32556	Mar 24, 2010
Nexframe Electrode DZap	5735Z	III	No	32556	Mar 24, 2010
Box of 5mT Tungs. El ectr.ARDB1	MER-5000T	III	Yes	32556	Mar 24, 2010

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Product category/ name and key to catalog number	Product catalog number	Class	Sterile	GMDN code (not mandatory)	Date added
microTargeting Electrodes FHC distributed	mT1234(x)(y) See key below	III	See key below	32556	Mar 24, 2010

1: electrode type
B: backloaded
D: differential
F: frontloaded
S: shielded

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

3: impedance
A: 500 Kohms (+/- 30%)
B: 1.0 Megohms (+/-20%) C: 5.0 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 1KHz

4: sterility
N: nonsterile
P: presterile

mTB
Electrode length: 100-300mm
Exposure: 2-50mm

mTD
Electrode length: 100-293mm
Differential length: 1-50mm
Protective tube length:
100-300mm

mTF
Electrode length: 100-300mm
Reach: 90mm-electrode
length less 10mm

mTS
Electrode length: 100-295mm
Reach: 1-50mm
Protective tube length:
100-300mm
Range of motion:
2-75mm

(x): customer specification
(y): customer specification
Variations in
length, exposure,
reach and range of motion

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MDD – Product List

Product category/ name and key to catalog number	Product catalog number	Class	Sterile	GMDN code (not mandatory)	Date added
mT Array Electrodes 6x Non Sterile	22335Z (alternative catalog number for MTDWZN(SP)(AR1) , see above)	III	No		Aug 12 2019
mT Array Electrodes 5x Sterile	22375Z (alternative catalog number for MTDWZP(SP)(AR1), see above)	III	Yes		Aug 12 2019
mT Array Frame Platinum 6X Non Sterile	25335Z (alternative catalog number for MTDPZN(PA)(AR4), see above)	III	No		Aug 12 2019
mT Array Frame Platinum 5X Sterile	25375Z (alternative catalog number for MTDPZP(PA)(AR4), see above)	III	Yes		Aug 12 2019
mT Frame Single Tungsten 6X Non Sterile	34325Z (alternative catalog number for MTDWZB(BP)(BP8), see above)	III	No		Aug 12 2019
mT Frame Single Tungsten 5X Sterile	34385Z (alternative catalog number for MTDWZP(BP)(BP8), see above)	III	Yes		Aug 12 2019
mT Single Frame Platinum 6x Non Sterile	35325Z (alternative catalog number for MTDPZN(EP)(BP8), see above)	III	No		Aug 12 2019
mT Single Frame Platinum 5X Sterile	35385Z (alternative catalog number for MTDPZP(EP)(BP8), see above)	III	Yes		Aug 12 2019
mT Platform Electrode Tungsten 6X Non Sterile	44335Z (alternative catalog number for MTDWZN(SP)(MP4) , see above)	III	No		Aug 12 2019
mT Platform Electrode Tungsten 5x Sterile	44375Z (alternative catalog number for MTDWZP(SP)(MP4) , see above)	III	Yes		Aug 12 2019
mT Platform Electrode Platinum 6X Non Sterile	45335Z (alternative catalog number for MTDPZN(PA)(MP4), see above)	III	No		Aug 12 2019
mT Platform Electrode Platinum 5X Sterile	45335Z (alternative catalog number for MTDPZN(PA)(MP4), see above)	III	Yes		Aug 12 2019

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MDD – Product List

Product category/ name and key to catalog number	Product catalog number	Class	Sterile	GMDN code (not mandatory)	Date added
microTargeting Electrodes Medtronic distributed					
Box of 5 array electrodes	22670	III	Yes	32556	Mar 24, 2010
Box of 5 single electrodes	34680	III	Yes	32556	Mar 24, 2010
Non Sterile Diff mT electrode	FC1002	III	No	32556	Mar 24, 2010
Non Sterile Diff. mT electrod	FC1003	III	No	32556	Mar 24, 2010
Sterile DZAP Array Insertion Electrode 5pk	FC2001	III	Yes	32556	Nov 7, 2011
Sterile DZAP Single Insertion Electrode 5pk	FC2002	III	Yes	32556	Nov 7, 2011
Sterile DZAP Single & Array Insertion Electrode 5pk	FC2003	III	Yes	32556	Nov 7, 2011
Sterile DZAP Single & Array Insertion Electrode 5pk	FC2004	III	Yes	32556	Nov 7, 2011
Box of 5 Pt Nexframe electrode	FC5000	III	Yes	32556	Mar 24 2010
Insertion and Protective Tubes FHC distributed					
Insertion tube	66-IT-x (see key below)	III	See key below	61854 62753	Mar 24 2010
Protective tube	66-PT-x (see key below)	III	See key below	61854 62753	Mar 24 2010
Array Tube Kit for Nexframe	MER-6000	III	No	61854	Mar 24 2010
Insertion tube	70-IT-x (see key below)	III	See key below	61854 62753	Mar 24 2010
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				

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MDD – Product List

Product category/ name and key to catalog number	Product catalog number	Class	Sterile	GMDN code (not mandatory)	Date added
Insertion and Protective Tubes Medtronic distributed					
Single Electrode Insertion Tube Set for microTargeting Drive or microTargeting STar Drive	FC1011	III	No	61854	Mar 24, 2010
Array Electrode Insertion tube w/stylette, frame	FC1012	III	No	61854	Mar 24, 2010
Array Electrode Insertion Tube Set for microTargeting Drive	FC1018	III	Yes	62753	Mar 24, 2010
Lead Insertion Tube w/ Stylet, Sterile	FC1019	III	Yes	62753	Mar 24 2010
Single Electrode Insertion Tube Set 5x 20mm Above Target	FC1036	III	Yes	62753	Nov 7, 2011
Array Lead Insert Tubes w/Styl	FC7140LI	III	Yes	62753	Mar 24 2010
STar Array Electrode Insertion Tube with Stylet 5x	FC8009	III	Yes	62753	Nov 7, 2011
STar Array Electrode Insertion Tube w/ Stylet 5x	FC9001	III	Yes	62753	Nov 7, 2011
Lead Insertion Tube with Stylet 5x	FC9002	III	Yes	62753	Nov 7, 2011
STar Single Electrode Insertion Tube 5x for use with Nexframe and STar Drive	FC9003	III	Yes	62753	Nov 7, 2011

Date of Issue: 27 May 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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MDD – Decision Report

Certificate No: 41318560-03
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	Certification audit was performed 12 December 2019 in Bowdoin by Alexander Crosby. The design dossier was reviewed 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 non conformities were noted during the audit, no open non-conformities remain from DD review.
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 "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