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:

FHC, Inc

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

Product Category:

- Neurological stereotactic surgery system and accessories
- Class I sterile devices

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

Certificate Number:
41313871-04

Initial Certification Date:
18 June 2006

Certificate Valid from:
29 April 2020

Certificate Expiry Date:
26 May 2024

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

Bob Andersson
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

29 April 2020
Signed Date

Intertek Semko AB
Box 1103, SE-164 22 Kista, Sweden
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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: 41313871-04
Issued to: **FHC, Inc.**
1201 Main Street
Bowdoin, Maine 04287
USA

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Class I sterile devices					
	66-EL-EC microTargeting Electrode cable, FHC distributed	I(s)	Yes		*
	FC1020 microTargeting Electrode cable, Medtronic distributed	I(s)	Yes		*
	66-EL-LP microTargeting Electrode cable, FHC distributed	I(s)	Yes		Oct 28, 2010
	C0230 microTargeting™ Electrode Cable	I(s)	Yes		Nov 29, 2018
	C0231 microTargeting™ Electrode Cable	I(s)	Yes		Nov 29, 2018
	66-EL-EC-01 microTargeting Electrode cable, FHC distributed	I(s)	Yes	32568	May 13, 2016
	70-CN-ET Sterile STar™ Insertion Tube Extractors	I(s)	Yes	32568	May 13, 2016
	FC8011 STar™ Array Insertion Tube Extractor	I(s)	Yes	32568	May 13, 2016
	66-AC-DC Leadloc Depth Stop	I(s)	Yes	32568	May 13, 2016
	66-DA-SD Sterile Drape Sleeves FHC distributed	I(s)	Yes		Feb 14, 2012
	FC1004 Sterile Drape Sleeves Medtronic distributed	I(s)	Yes		Feb 14, 2012
	66-WP-BKS Sterile, WayPoint surgical tools	I(s)	Yes	32568	Sept 9, 2009
	66-WP-IKS Sterile, WayPoint surgical tools	I(s)	Yes	32568	Sept 9, 2009

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

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	66-WP-SKS Sterile, WayPoint surgical tools	I(s)	Yes	32568	Sept 9, 2009
	Nexprobe® NP-1000	I(s)	Yes		Nov 19, 2019
Neurosurgical Stereotactic surgery system and accessories					
Intraoperative neurophysiological recording and stimulating device	MT-GL4K microTargeting Guideline 4000	IIa	No		*
	MT-LPP microTargeting™ Guideline 4000 5.0 System	IIa	No		Oct 28, 2010
	C0220 microTargeting™ Guideline 4000 5.0 LF Interface	IIa	No		Dec 12, 2018
	C0258 Guideline 4000™ 5.0 Resident Expert Software Module	IIa	No		Nov 19, 2019
	C0259 Resident Expert Kinetic Motion Detector	IIa	No		Nov 19, 2019
WayPoint Stereotactic System Implant Tools	66-WP-ANx FHC distributed: 66-WP-ANx (where x designates the type of Anchor) 66-WP-AN, 66-WP-AN1, 66-WP-AN2, 66-WP-AN5	IIa	No	32568	Sept 9, 2009
	66-WP-NV(4.x) WayPoint Navigator Stereotactic System, Software (pre-installed laptop)	IIa	No	32568	Oct 03, 2018
	66-WP-Px FHC distributed: 66-WP-Px (where x designates the type of Pilot Drill Bit) 66-WP-P2,66-WP-PD, 66-WP-PDS	IIa	No	32568	Sept 9, 2009

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Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	MP-KIT-P-XX WayPoint™ Stereotactic System (microTargeting TM Platform - where XX designates the type of platform; single, bilateral, unilateral, staged etc.)	IIa	No	32568	June 16, 2017
	Waypoint™ Navigator Software (V4.x) different licenses C0239 C0241 C0242 C0243 C0244	IIa	No		Aug 12, 2019
NexframeStereotactic System and accessories	Nexframe® System DB-2040	IIa	Yes	32568	Nov 19, 2019
	Nexdrive™ Micropositioning Drive MI-1000	IIa	Yes		Nov 19, 2019
	Nexdrive™ Micropositioning Drive MI-2000	IIa	Yes		Nov 19, 2019
	Unibody™ Bone Fiducial (7mm) FM-4007	IIa	Yes		Nov 19, 2019
	Unibody™ Bone Fiducial (10mm) FM-4010	IIa	Yes		Nov 19, 2019
	Unibody™ Bone Fiducial (13 mm) FM-4013	IIa	Yes		Nov 19, 2019
	Nexframe Screw SR-10	IIa	Yes		Nov 19, 2019

* Product added before September 9, 2009.

Date of Issue: 28 August 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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