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CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

FHC, Inc.

Main Site: 1201 Main Street, Bowdoin, Maine, 04287, United States (FIN F000821)

Additional site:
180 Main Street, Greenville, Pennsylvania, 16125, United States (FIN F001989)

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

Canada: Medical Devices Regulations – Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68; PMD Act

The management system is applicable to:

The design, manufacture, distribution, installation, training, and servicing of neurosurgical systems (some components of which are supplied in a sterile condition) manufactured by or for the company and used to target and position electrodes and other instruments for the purpose of amplifying extracellular potentials, stimulating responses, and/or ablating target areas, as well as acquiring and analyzing data and the introduction or removal of substances and tissues to or from the nervous system.

Additional site: The manufacture, distribution, and training of platform stereotactic systems.

Certificate Number:
0080451-01

Initial Certification Date:
2018-09-01

Date of Certification Decision:
2021-08-12

Certification Effective Date:
2021-08-31

Certification Expiry Date:
2024-08-31

ISO 13485:2016 CERTIFICATION TM

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

intertek

Calin Moldovean
President, Business Assurance

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