

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







Calin Moldovean President, Business Assurance

Intertek Testing Services NA, Inc. 900 Chelmsford Street Lowell, MA, USA 01851





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 organization 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. Validity of this certificate may be verified at http://www.intertek.com/business-assurance/certificate-validation/