

BIOTRONIK SE & Co. KG

Woermannkehre 1

12359 Berlin, Germany

www.biotronik.com

Sep 30, 2021

Equipment Authorization Branch

Federal Communications Commission

Subject: Confidentiality Request pertaining to the certification of FCC ID: QRI-SCSIPG

To Whom It May Concern,

Biotronik requests that the information contained in the items enumerated below pertaining to the above-referenced application be withheld from public disclosure in accordance with Commission's Rules, 47 C.F.R. § 0.457(d) and 0.459, following grant of the application.

The confidential information is embodied in electronic schematics, operational description, parts lists, block diagram, and internal photographs of a device designed and manufactured by Biotronik.

These highly confidential information could convey trade secrets pertaining to manufacturing and design techniques. The information for which confidentiality is sought is employed in the design and manufacture of medical device systems that are offered on a highly competitive basis. Customers for this equipment have a variety of competing sources of supply from both domestic and foreign suppliers. Disclosure would, in effect, give away the intellectual properties of Biotronik to competitors.

Disclosure would also offer competitors additional unwarranted insight into the state of product development thereby allowing such competitors an advantage that would not be available to Biotronik.

The information for which confidential treatment is sought is kept confidential by Biotronik and not made available to third parties except pursuant to arrangements designed to prevent public disclosure. To the knowledge of those preparing this application, the information has not been disclosed publicly heretofore. The protection sought is narrowly drawn and pertains to certain specific implementations of the technology incorporated into the device for which certification is sought.

Long-Term Confidentiality

The materials set forth in the following exhibits, which are segregated from the non-confidential exhibits of the application, are the ones for which Biotronik requests Long-Term Confidentiality:

- 1) Internal Photos
- 2) Schematics
- 3) Block Diagram
- 4) Theory of Operation / Operational description

Following the Equipment Authorization Confidentiality Request Procedures as described in KDB Guidance 726920 D01 of April 8th 2016, Internal Photos may be held Long-Term Confidential under the condition that the circuit board or internal components are not accessible to users.

Biotronik's Prospera Neuro SCS IPG, which is the subject of this future FDA filing, are not available to the public. The devices are Class 3 devices regulated by the FDA and are available by prescription only by health care professionals and implanted directly in the patient. As the devices are sealed hermetically by a titanium can, opening the device is not possible without destroying it.

Therefore, the equipment to which this Long-Term Confidentiality request pertains satisfies this criterion.

#### Short-Term Confidentiality

The materials set forth in the following exhibits, which are also segregated from the non-confidential exhibits of the application, are the ones for which Biotronik requests Short-Term Confidentiality for a period of 180 days from the date of the grant:

- 1) External Photos
- 2) Test Setup Photos
- 3) User Manuals

Respectfully,



Sep 30, 2021

Gunnar Boersch

Senior Team Manager Regulatory Affairs