EC Declaration of Conformity

Manufacturers Name & Address	FR Rådgivende Ingeniører Aps Telehøjen 6 5220 Odense SØ Denmark
SRN (Single Registration Number)	DK-MF-000011892
Basic UDI-DI	5745000245ATD49
Name of the Device (s)	ATD
Intended use:	ATD is intended to alleviate essential tremor and Parkinson's tremor
Device model(s)	ATD
Classification	Class I (according to Annex VIII, Chapter III, rule 1 and rule 13)
Notified Body name and address:	Pending
Notified Body Identification number:	Pending
Conformity procedure used	Annex IX
Standards	Conformity to the general safety and performance requirements have been demonstrated by using the following standards:
ISO 13485:2016	Medical devices - Quality management systems Requirements for regulatory purposes
ISO14971:2019	Medical devices - Application of risk management to medical devices
IEC 60601-1-2:2015	Medical electrical equipment - Part 1: General requirements for safety. 2 Collateral Standard: Electromagnetic compatibility - requirements and tests
ISO15223-1:2016	Medical devices. Symbols to be used with medical device labels, labeling and information to be supplied. General requirements
Conformity assessment route	The following procedures are used for the CE-labeling of their products according the Regulation MDR 2017/745: Class I: EC conformity declaration according to annex II + annex III

This declaration of conformity is issued under the sole responsibility of Antitremor, FR Rådgivende Ingeniører. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices.

Signature:

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Finn Rasmussen
CEO
Antitremor FR Rådgivende Ingeniører Aps
Telehøjen 6
DK-5220 Odense SØ

Place and date (yyyy-mm-dd) of issue:

Odense 2024-05-23
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