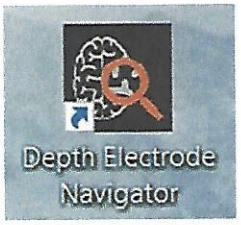
EU DECLARATION OF CONFORMITY DENS

1. Version DENS 1.0.4 (unique identification of the product)
2. Clinical Neuro-Science projects, De Wittenkade 283, 1052 DD Amsterdam, Netherlands
3. This declaration of conformity is issued under the sole responsibility of the manufacturer: Clinical Neuro-Science projects, De Wittenkade 283, 1052 DD Amsterdam, Netherlands
4. Object of the declaration: shortcut to identify the application



5. The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation legislation: Medical Device Directive - Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.
6. References to the relevant harmonised standards used, or references to the specifications in relation to which conformity is declared.

   Relevant regulations of the Medical Device Directory to perform the conformity assessment of the device are:

   - Article 1 paragraph 2(a) MDD: Verify whether the product falls within the definition of a medical device.
   - Article 9 and Annex IX MDD: Determine the class of the device.
   - Article 3 and Annex I of the MDD: "The devices must meet the essential requirements set out in Annex I which apply to them, taking account of the intended purpose of the devices concerned."
   - Annex X MDD: Compliance with the essential requirements must be demonstrated by a clinical evaluation (Article 11.5 MDD juncto Annex VII, chapter 3 MDD juncto Annex X MDD).
   - Article 11: As a manufacturer, you draw up technical documentation. To do this, use the instructions in the appendices (II to VII) of the guideline that applies to your product and risk class.
   - Article 11.5 and Annex VII MDD: Conformity assessment procedure for class I medical device (Section 3).

- Article 11.5 and Annex VII MDD: Conformity assessment procedure for class I medical device (Section 4).
- Article 5: Article 11.5 and Annex VII MDD: Conformity assessment procedure for class I medical device. "The technical documentation must include the results of the risk analysis and a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive if the standards referred to in Article 5 have not been applied in full".
- Chapter 4 of Annex VII MDD and Annex X MDD: Post Market Surveillance.
- Annex VII MDD: EC DECLARATION OF CONFORMITY
- Article 17 and Annex XII MDD: Affix the CE marking visible, legible and indelible.

7. Further remarks: DENS is according to the MDD a class I medical device. According to the MDD it is then possible to obtain a valid EC declaration of conformity by means of a self-assessment, the medical device doesn't need to be verified by an independent body. The MDD sets requirements to perform the conformity assessment of the device (point 6). This includes estimating and documenting the possible risks when using the device and a quality management system.

Signed for and on behalf of: Clinical Neuro-Science projects

(place and date of issue): Amsterdam, 2021 May 12

(name, function): P.P.W. Ossenblok, Chair of the Board of Directors

(signature):