BESA Connectivity 2.0 - IntendedUse+ProductClassification

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Description:

This document contains information concerning the intended use, intended purpose, and the product classification of BESA Connectivity 2.0.0.0.

Table of Content

Product Name

BESA Connectivity 2.0.0.0

Intended Use

- BESA Connectivity 2.0.0.0 is intended for the offline analysis of previously recorded EEG and MEG data files of human beings, and NOT of animal beings.
- BESA Connectivity 2.0.0.0 is a stand-alone software product compatible with personal computers running under a Windows operating system.
- BESA Connectivity 2.0.0.0 is intended to be run independently of the EEG and MEG acquisition and review programs of other manufacturers.
- BESA Connectivity 2.0.0.0 must not be used as monitoring software for vital human functions, for example, in:
    - Intensive care units
    - Neurosurgical units
- BESA Connectivity 2.0.0.0 is not for commercial use, e.g. for fee-based analysis services.

Intended Purpose

- The purpose of BESA Connectivity 2.0.0.0 is the use as a tool for performing time-frequency analysis and brain connectivity analysis of EEG and MEG data, for research purposes only.
- It is not allowed to use BESA Connectivity 2.0.0.0 in a medical environment, or with any intended medical purpose whatsoever.

Intended User

- The intended user is a researcher who is a neuroscience professional with a thorough understanding of the mechanisms underlying the generation of electrophysiological potentials in the human brain. The intended user is expected to be literate in the usage of computer programs in the Windows environment.
- BESA Connectivity 2.0.0.0 is only to be used by appropriate trained specialist personnel who also have an understanding of English sufficient to enable them to read the instructions for use documents and to operate the software.
- The BESA GmbH assumes no liability for unauthorized access to this product or unauthorized use. Children, layman and patients shall not use the product.

Conclusion of Assessment of Medical Device Class and Software safety classification

BESA Connectivity 2.0.0.0 is not a medical device within the scope of the regulation (EU) 2017/745 on medical devices (MDR).