BESA Research 7.1 - Declaration of Conformity

Declaration of Conformity

Confirmation is hereby given that the software

BESA® Research 7.1.3.1

together with all options and modules, conforms to the essential requirements stipulated by the Council Directive regarding the harmonization of statutory requirements of the member states on Medical Devices 93/42/EEC (MDD), as amended by Directive 2007/47/EC, and also conforms to applicable requirements of Regulation (EU) 2017/745 (MDR). The conformity assessment was performed to MDD Annex II excluding (4) and confirmed by EC Certificate Registration No. HD 1785257-1.

This declaration is supported by the Quality System approval to EN ISO 13485:2016 issued by TÜV Rheinland LGA Products GmbH and confirmed by certificate registration number: SX 1785257-1.

Intended Purpose

BESA Research 7.1.3.1 is intended to be used as an additional tool for the clinical evaluation of data for the purpose of analyzing epileptiform EEG and MEG data.

Medical Device Class

BESA Research 7.1.3.1 is an active medical device	according to MDD 93-42-EEC, Article 1, Definitions
Designed for short term use	according to MDD 93-42-EEC ANNEX IX CLASSIFICATION CRITERIA, 1.1. Duration
Class IIa	according to MDD 93-42-EEC, Annex IX, III. CLASSIFICATION, rule 10, indent 3

Software safety classification

Class B	according to IEC 62304:2006/AMD1:2015

Medical Device Nomenclature Codes

UMDNS code:	16-307 (GMDN: 35163)
GMDN collective term:	CT112 Software, application program
Basic UDI:	426236423BESAResFH
UDI-DI:	(1)4262364230004
UDI-PI:	(8012)07010301
The product is marked with: CE 0197	The number 0197 represents the identification number of the Notified Body: TÜV Rheinland LGA Products GmbH, Tillystraße 2, 90431 Nuernberg, Germany

Aforesaid is declared under the sole responsibility of the manufacturer:

BESA GMBH
Freihamer Str. 18
82166 Graefelfing, Germany

Single Registration Number (SRN):
DE-MF-000020923

This declaration is valid for all products with version number as mentioned above, or until withdrawn by BESA GmbH as manufacture due to modification of product or of requirements or of certificate or due to end of lifecycle for the product.

Graefelfing, October 23rd, 2024

Michael Kornwebel

Quality Manager

BESA GmbH

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