

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. CE 685187
Issued To: **MJN Neuroserveis SL**
Av. Juan Carlos I, 184 bajos derecha
Blanes (Girona)
17300
Spain

In respect of:

Design and manufacture of active devices for assessing the risk of epileptic seizures

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2020-04-29**

Date: **2020-04-29**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

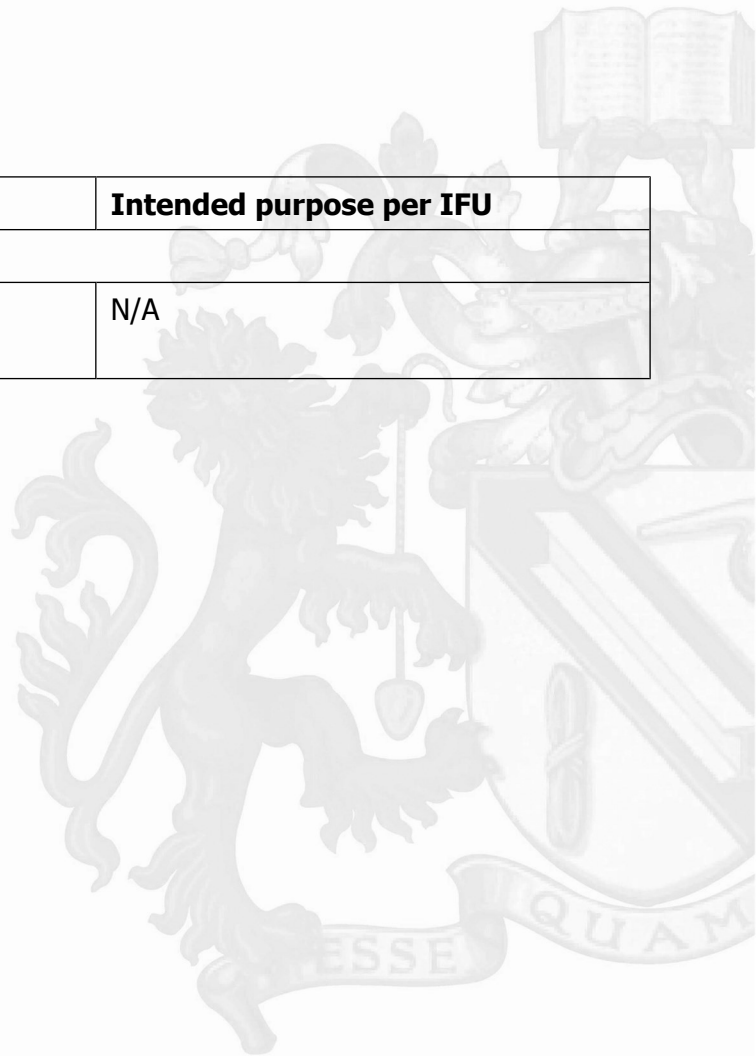
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Supplementary Information to CE 685187

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NBOG code(s)	Device Name	Intended purpose per IFU
Class IIa		
MD 1302 MDS 7010	MJN-SERAS	N/A



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