



EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 777314 R000

Manufacturer: MJN Neuroserveis SL

Address:

Av. Juan Carlos I 184 bajos derecha 17300 Blanes Girona Spain

Single Registration Number: ES-MF-000020022

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

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

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: 2024-11-29 Starting Validity Date: 2024-11-29

Current Issue Date: **2024-11-29** Expiry Date: **2029-11-28**

...making excellence a habit."

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

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