

Title: DECLARATION OF CONFORMITY – Appendix 2
Number: WI-190003 Revision: 7 CO Number: 103095152
Type: Non PPE Class: Work Instruction Release Level: Production
ICP Monitoring Kits and Accessory Kit DD-004, Rev H

CODMAN NEURO



Declaration of Conformity

ICP Monitoring Kits and Accessory Kit DD-004, Rev H

Manufacturer:

Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, MA 02767-0350
USA

Authorised representative
Johnson & Johnson Medical Ltd.
Pinewood Campus,
Nine Mile Ride,
Wokingham, RG40 3EW
United Kingdom

Notified Body:

BSi
Identification Number: 0086

Full Quality Assurance Certificate CE00484
Design Examination Certificate CE01584

MDD Annex II including Section 4

Products:

See attached list

Classification: Class III by Rule 7 of Annex IX of the MDD 93/42/EEC

We declare that the above-mentioned products meet the provisions of the *legislation transposing European Medical Devices Directive 93/42/EEC* concerning Medical Devices into the laws of the European Economic area. All supporting documentation is available under the premises of the manufacturer.

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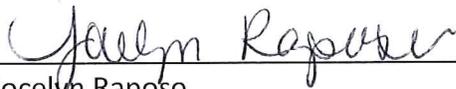
Codman & Shurtleff Inc., being the manufacturer/design site, declares to the best of its knowledge that the products covered by this declaration conform to the provisions of the recast RoHS Directive (2011/65/EU) for medical devices (RoHS2), as transposed into National Law.

Start of CE Marking: See Attached



Megan Palumbo
Regulatory Affairs Project Lead

04/MAY/2017
DD/MMM/YYYY



Jocelyn Raposo
Regulatory Affairs Associate Director

04/may/2017
DD/MMM/YYYY

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PRODUCT CODE	DESCRIPTION	Sterile/ Non- Sterile	CE MARK DATE	GMDN CODE	GMDN CODE DESCRIPTION
Manufacturing Site: Codman & Shurtleff, Inc. Raynham, MA					
82-6724	Double Lumen Skull Bolt Kit	Sterile	Jan 2009	16763	Intracranial pressure monitor
62-6633	Codman Microsensor Ventricular Catheter Kit with Tuohy-Borst Adapter	Sterile	28-Aug-2015	16763	Intracranial pressure monitor
62-6653	Codman Microsensor Ventricular Catheter Kit	Sterile	28-Aug-2015	16763	Intracranial pressure monitor
Manufacturing Site: Medos SARL, LeLocle, Switzerland					
NS9011	Single Lumen Skull Bolt Kit	Sterile	March 2008	16763	Intracranial pressure monitor
62-6631	Codman Microsensor Basic Kit	Sterile	28-Aug-2015	16763	Intracranial pressure monitor
62-6632	Codman Microsensor Plastic Skull Bolt Kit	Sterile	28-Aug-2015	16763	Intracranial pressure monitor
62-6638	Codman Microsensor Metal Skull Bolt Kit	Sterile	28-Aug-2015	16763	Intracranial pressure monitor