

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**

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**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.

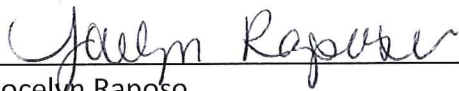
**Start of CE Marking: See Attached**



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