

Title: DECLARATION OF CONFORMITY – Appendix 2

Number: WI-190003

Revision: 7

CO Number: 103095152

Type: Non PPE

Class: Work Instruction

Release Level: Production

External Drainage Systems # DD-007 Rev. D

CODMAN NEURO

PART OF THE *Johnson & Johnson* FAMILY OF COMPANIES

Declaration of Conformity

External Drainage Systems # DD-007 Rev. D

Manufacturer:

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

Authorised representative

Codman

A division of Johnson & Johnson Medical Ltd.
Pinewood Campus,
Nine Mile Ride,
Wokingham, RG40 3EW
United Kingdom

Notified Body:

BSI

Identification Number: 0086

Design Examination Certificate CE01068 & CE02289

Full Quality Assurance Certificate CE00484

MDD Annex II including Section 4

Products:

See attached list

Classification: Class III, 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.

Title: DECLARATION OF CONFORMITY – Appendix 2

Number: WI-190003

Revision: 7

CO Number: 103095152

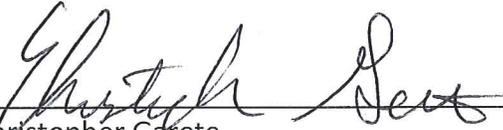
Type: Non PPE

Class: Work Instruction

Release Level: Production

External Drainage Systems # DD-007 Rev. D

Start of CE Marking: See Attached



Christopher Garete
Regulatory Affairs Specialist II

07-Aug-2017
DD/MMM/YYYY



Jocelyn Raposo
Associate Director Regulatory Affairs

07/Aug/2017
DD/MMM/YYYY

Title: DECLARATION OF CONFORMITY – Appendix 2

Number: WI-190003

Revision: 7

CO Number: 103095152

Type: Non PPE

Class: Work Instruction

Release Level: Production

External Drainage Systems # DD-007 Rev. D

PRODUCT CODE	DESCRIPTION	Sterile/ Non- Sterile	CE MARK DATE	GMDN CODE	GMDN CODE DESCRIPTION
<u>Manufactured by Medos Sarl</u>					
82-1730	EDS 3 External Drainage System with Ventricular Catheter	Sterile	8-Dec.-1995	61798	Ventricular Cerebrospinal Fluid Catheter/ External Drainage Kit
82-1735	EDS 3 CSF Clear Ventricular Catheter	Sterile	8-Dec.-1995	61399	Intracerebral infusion/drainage catheter, short-term
82-1739	EDS 3 CSF Clear with Barium Stripe Large Lumen Ventricular Catheter	Sterile	8-Dec.-1995	61399	Intracerebral infusion/drainage catheter, short-term
82-1706	Codman Lumbar External Drainage Catheter with Tuohy Needle	Sterile	8-Dec.-1995	47079	Spinal infusion/drainage catheter
<u>Manufactured by Codman & Shurtleff, Inc.</u>					
82-1705	Codman External Drainage Catheter Set	Sterile	8-Dec.-1995	61399	Intracerebral infusion/drainage catheter, short-term
82-1707	Codman Lumbar Drainage Catheter Kit II	Sterile	8-Dec.-1995	47079	Spinal infusion/drainage catheter