

CODMAN NEURO



ARTICLE 12 DECLARATION OF THE MEDICAL DEVICE DIRECTIVE (93/42/EEC)

To Whom It May Concern:

The following product is placed on the market as a system and:

- a. Codman has verified the mutual compatibility of the devices in accordance with the manufacturer's instruction and Codman has carried out the operations in accordance with these instructions; and
- b. Codman has packaged the system and supplied relevant information to users incorporating relevant instructions from the manufacturers; and
- c. The whole activity is subjected to appropriate methods of internal control and inspection.

System Code and Revision: 82-1738

System Description: Lumbar Catheter Kit II (82-1707) packaged with External Drainage System 3 No catheter (82-1731)

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

Authorized Representative: Johnson & Johnson Medical Ltd.
Pinewood Campus,
Nine Mile Ride,
Wokingham, RG40 3EW
United Kingdom

Classification & Rule: Class III by Rule 7

GMDN Description: Cerebrospinal Fluid Drainage Kit, Lumbar & Ventricular cerebrospinal fluid catheter/external drainage kit

GMDN Code: 48189 & 61798

Title: DECLARATION OF CONFORMITY – Appendix 3

Number: WI-190003

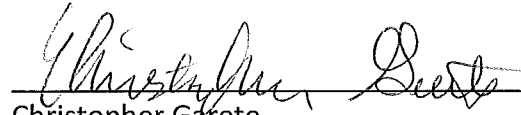
Revision: 7

CO Number: 103095152

Type: Non PPE

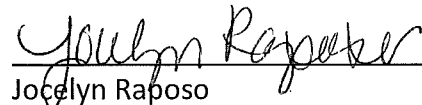
Class: Work Instruction

Release Level: Production



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16-Dec-2015
16/DEC/2015



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16-Dec-2015
16/DEC/2015

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System Description:

PRODUCT CODE	DESCRIPTION	Sterile/ Non-Sterile	DATE	GMDN CODE	GMDN CODE DESCRIPTION
821738	Lumbar Catheter Kit II (82-1707) with EDS 3 CSF External Drainage System (82-1731)	Sterile	02-FEB-2006	48189	Cerebrospinal Fluid Drainage Kit, Lumbar
				61798	Ventricular cerebrospinal fluid catheter/external drainage kit
Note: 82-1738 is the combination of 82-1707 and 82-1731 packaged together as a System/Procedure Pack under Article 12. The information below is supporting information for the individual 82-1707 and 82-1731 products.					
82-1707	Lumbar Drainage Catheter Kit II	Sterile	07-APR-1999	48189	Cerebrospinal Fluid Drainage Kit, Lumbar
82-1731	CSF External Drainage System 3	Sterile	16-DEC-2003	61798	Ventricular cerebrospinal fluid catheter/external drainage kit