

CODMAN NEURO



Declaration of Conformity

Hydrocephalus Shunt Systems and Components # DD-015 Rev F

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

**Design Examination Certificates: CE01069, CE01070, CE01072, CE01196, CE01239, and
CE01495**

Full Quality Assurance Certificate: CE00484

MDD Annex II including Section 4

Products:

See attached list

Classification: Class III by Rule 8 of Annex IX of the MDD 93/42EEC

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

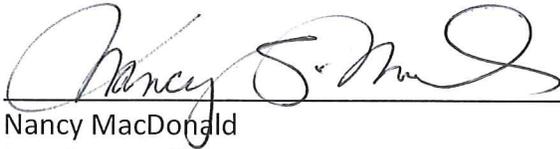
Type: Non PPE

Class: Work Instruction

Release Level: Production

Hydrocephalus Shunt System and Components DD-015 Rev F

Start of CE Marking: See Attached



Nancy MacDonald

Regulatory Affairs Manager

06/09/2017
DD/MM/YYYY



Jocelyn Raposo

Associate Director, Regulatory Affairs

07/09/2017
DD/MM/YYYY

Title: DECLARATION OF CONFORMITY – Appendix 2

Number: WI-190003

Revision: 7

CO Number: 103095152

Type: Non PPE

Class: Work Instruction

Release Level: Production

Hydrocephalus Shunt System and Components DD-015 Rev F

PRODUCT CODE	DESCRIPTION	Sterile/Non-Sterile	CE MARK DATE	GMDN CODE	GMDN CODE DESCRIPTION
82-1630	Ventricular Catheter -Reservoir, 3cm	Sterile	08-DEC-1995	61376	Intracerebral infusion/drainage catheter, long-term
82-1632	Ventricular Catheter -Reservoir, 4 cm	Sterile	08-DEC-1995	61376	Intracerebral infusion/drainage catheter, long-term
82-1634	Ventricular Catheter -Reservoir, 5 cm	Sterile	08-DEC-1995	61376	Intracerebral infusion/drainage catheter, long-term
82-1636	Ventricular Catheter -Reservoir, 6 cm	Sterile	08-DEC-1995	61376	Intracerebral infusion/drainage catheter, long-term
82-1638	Ventricular Catheter -Reservoir, 7 cm	Sterile	08-DEC-1995	61376	Intracerebral infusion/drainage catheter, long-term
82-1640	Ventricular Catheter -Reservoir, 8 cm	Sterile	08-DEC-1995	61376	Intracerebral infusion/drainage catheter, long-term
82-1642	Ventricular Catheter -Reservoir, 9 cm	Sterile	08-DEC-1995	61376	Intracerebral infusion/drainage catheter, long-term
82-1644	Ventricular Catheter -Reservoir, 10 cm	Sterile	08-DEC-1995	61376	Intracerebral infusion/drainage catheter, long-term
82-1650	Ventricular Right Angle Catheter, 15 cm	Sterile	08-DEC-1995	61376	Intracerebral infusion/drainage catheter, long-term
82-1652	Ventricular Right Angle Catheter, 3 cm	Sterile	08-DEC-1995	61376	Intracerebral infusion/drainage catheter, long-term
82-1654	Ventricular Right Angle Catheter, 4 cm	Sterile	08-DEC-1995	61376	Intracerebral infusion/drainage catheter, long-term
82-1656	Ventricular Right Angle Catheter, 5 cm	Sterile	08-DEC-1995	61376	Intracerebral infusion/drainage catheter, long-term
82-1658	Ventricular Right Angle Catheter, 6 cm	Sterile	08-DEC-1995	61376	Intracerebral infusion/drainage catheter, long-term
82-1660	Ventricular Right Angle Catheter, 7 cm	Sterile	08-DEC-1995	61376	Intracerebral infusion/drainage catheter, long-term
82-1662	Ventricular Right Angle Catheter, 8 cm	Sterile	08-DEC-1995	61376	Intracerebral infusion/drainage catheter, long-term
82-1664	Ventricular Right Angle Catheter, 9 cm	Sterile	08-DEC-1995	61376	Intracerebral infusion/drainage catheter, long-term
82-1666	Ventricular Right Angle Catheter, 10	Sterile	08-DEC-1995	61376	Intracerebral infusion/drainage catheter,

Title: DECLARATION OF CONFORMITY – Appendix 2

Number: WI-190003

Revision: 7

CO Number: 103095152

Type: Non PPE

Class: Work Instruction

Release Level: Production

Hydrocephalus Shunt System and Components DD-015 Rev F

PRODUCT CODE	DESCRIPTION	Sterile/Non-Sterile	CE MARK DATE	GMDN CODE	GMDN CODE DESCRIPTION
	cm				long-term
82-1670	Holter Distal Atrial Catheter, Type A, Barium, 45 cm	Sterile	08-DEC-1995	61158	Atrial cerebrospinal fluid catheter
82-1672	Holter Distal Atrial Catheter, Type B, Barium Two Piece, Total Length 38cm	Sterile	08-DEC-1995	61158	Atrial cerebrospinal fluid catheter
82-1674	Holter Distal Atrial Catheter, Type C, Barium, Total Length 42 cm	Sterile	08-DEC-1995	61158	Atrial cerebrospinal fluid catheter
82-1676	Type E, Barium, Total Length 48 cm	Sterile	08-DEC-1995	61158	Atrial cerebrospinal fluid catheter
82-1678	Type H, Barium, Total Length 41 cm	Sterile	08-DEC-1995	61158	Atrial cerebrospinal fluid catheter
82-1201	Accuflo Vent Catheter	Sterile	08-DEC-1995	61376	Intracerebral infusion/drainage catheter, long-term
82-1203	Accuflo Clear Vent Catheter	Sterile	08-DEC-1995	61376	Intracerebral infusion/drainage catheter, long-term
82-1221	Accuflo Dotted Vent Catheter	Sterile	08-DEC-1995	61376	Intracerebral infusion/drainage catheter, long-term
82-1231	Accuflo Barium RA Vent Catheter	Sterile	08-DEC-1995	61376	Intracerebral infusion/drainage catheter, long-term
82-1232	Accuflo Barium RA Vent Catheter	Sterile	08-DEC-1995	61376	Intracerebral infusion/drainage catheter, long-term
82-1233	Accuflo Barium RA Vent Catheter	Sterile	08-DEC-1995	61376	Intracerebral infusion/drainage catheter, long-term
82-1234	Accuflo Barium RA Vent Catheter	Sterile	08-DEC-1995	61376	Intracerebral infusion/drainage catheter, long-term
82-3041	Hakim Vent Catheter	Sterile	Prior to: 21-MAY-2002	61376	Intracerebral infusion/drainage catheter, long-term
82-3044	Codman Atrial Shunt	Sterile	Prior to: 21-MAY-2002	61158	Atrial cerebrospinal fluid catheter
82-1698	Holter Lumboperitoneal Catheter	Sterile	08-DEC-1995	61523	Lumboperitoneal shunt
82-1699	Holter Lumboperitoneal Catheter	Sterile	08-DEC-1995	61523	Lumboperitoneal shunt
82-6200	James Lumboperitoneal Catheter	Sterile	08-DEC-1995	61523	Lumboperitoneal shunt

Title: DECLARATION OF CONFORMITY – Appendix 2

Number: WI-190003

Revision: 7

CO Number: 103095152

Type: Non PPE

Class: Work Instruction

Release Level: Production

Hydrocephalus Shunt System and Components DD-015 Rev F

PRODUCT CODE	DESCRIPTION	Sterile/Non-Sterile	CE MARK DATE	GMDN CODE	GMDN CODE DESCRIPTION
82-6201	James Lumboperitoneal catheter	Sterile	08-DEC-1995	61523	Lumboperitoneal shunt
82-6202	James Lumboperitoneal catheter	Sterile	08-DEC-1995	61523	Lumboperitoneal shunt
82-8501	Reservoir w Kit-53 cm Low Pressure	Sterile	19-FEB-1996	45694	Ventriculoperitoneal shunt
82-8502	Reservoir w Kit-53 cm Med Pressure	Sterile	19-FEB-1996	45694	Ventriculoperitoneal shunt
82-8511	Reservoir w Kit-62 cm Low Pressure	Sterile	19-FEB-1996	45694	Ventriculoperitoneal shunt
82-8512	Reservoir w Kit-62 cm Med Pressure	Sterile	19-FEB-1996	45694	Ventriculoperitoneal shunt
82-8521	Reservoir w Kit-78 cm Low Pressure	Sterile	19-FEB-1996	45694	Ventriculoperitoneal shunt
82-8522	Reservoir w Kit-78 cm Med Pressure	Sterile	19-FEB-1996	45694	Ventriculoperitoneal shunt
82-8531	Reservoir w Kit-90 cm Low Pressure	Sterile	19-FEB-1996	45694	Ventriculoperitoneal shunt
82-8532	Reservoir w Kit-90 cm Med Pressure	Sterile	19-FEB-1996	45694	Ventriculoperitoneal shunt
82-8533	Reservoir w Kit-90 cm High Pressure	Sterile	19-FEB-1996	45694	Ventriculoperitoneal shunt
82-8541	Reservoir w Kit-102 cm Low Pressure	Sterile	19-FEB-1996	45694	Ventriculoperitoneal shunt
82-8542	Reservoir w Kit-102 cm Med Pressure	Sterile	19-FEB-1996	45694	Ventriculoperitoneal shunt
82-8543	Reservoir w Kit-102 cm High Pressure	Sterile	19-FEB-1996	45694	Ventriculoperitoneal shunt
82-3001	Hakim Precision Valve Very Low	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3002	Hakim Precision Valve Low	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3003	Hakim Precision Valve M L	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3004	Hakim Precision Valve M H	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt

Title: DECLARATION OF CONFORMITY – Appendix 2

Number: WI-190003

Revision: 7

CO Number: 103095152

Type: Non PPE

Class: Work Instruction

Release Level: Production

Hydrocephalus Shunt System and Components DD-015 Rev F

PRODUCT CODE	DESCRIPTION	Sterile/Non-Sterile	CE MARK DATE	GMDN CODE	GMDN CODE DESCRIPTION
82-3005	Hakim Precision Valve High	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3006	Hakim Precision Valve Unitized	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3007	Hakim Precision Valve Unitized	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3008	Hakim Precision Valve Unitized	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3009	Hakim Precision Valve Unitized	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3010	Hakim Precision Valve Unitized	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3016	Infant Hakim Precision Valve	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3017	Infant Hakim Precision Valve	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3018	Infant Hakim Precision Valve	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3019	Infant Hakim Precision Valve	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3020	Infant Hakim Precision Valve	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3021	Hakim Precision Micro	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3022	Hakim Precision Micro	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3023	Hakim Precision Micro	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3024	Hakim Precision Micro	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3025	Hakim Precision Micro	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3035	Hakim Precision Micro	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3036	Hakim Precision Micro	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3037	Hakim Precision Micro	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3038	Hakim Precision Micro	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3039	Hakim Precision Micro	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3100	Hakim Programmable	Sterile	Prior to: 21-MAY-2002	35965	Ventriculo-peritoneal/atrial shunt valve
82-3101	Infant Programmable	Sterile	Prior to: 21-MAY-2002	35965	Ventriculo-peritoneal/atrial shunt valve
82-3111	Hakim Programmable	Sterile	Prior to: 21-MAY-2002	35965	Ventriculo-peritoneal/atrial shunt valve

Title: DECLARATION OF CONFORMITY – Appendix 2

Number: WI-190003

Revision: 7

CO Number: 103095152

Type: Non PPE

Class: Work Instruction

Release Level: Production

Hydrocephalus Shunt System and Components DD-015 Rev F

PRODUCT CODE	DESCRIPTION	Sterile/Non-Sterile	CE MARK DATE	GMDN CODE	GMDN CODE DESCRIPTION
82-3113	Hakim Programmable Micro	Sterile	Prior to: 21-MAY-2002	35965	Ventriculo-peritoneal/atrial shunt valve
82-3114	Hakim Programmable Micro	Sterile	Prior to: 21-MAY-2002	35965	Ventriculo-peritoneal/atrial shunt valve
82-3136	Programmable Valve System	Sterile	Prior to: 21-MAY-2002	35965	Ventriculo-peritoneal/atrial shunt valve
82-3146	Programmable Valve Unitized	Sterile	Prior to: 21-MAY-2002	35965	Ventriculo-peritoneal/atrial shunt valve
82-3148	Programmable Valve Unitized	Sterile	Prior to: 21-MAY-2002	35965	Ventriculo-peritoneal/atrial shunt valve
82-3261	Precision Valve Unitized	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3262	Precision Valve Unitized	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3263	Precision Valve Unitized	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3264	Precision Valve Unitized	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3265	Precision Valve Unitized	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3281	Precision Valve Unitized	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3282	Precision Valve Unitized	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3283	Precision Valve Unitized	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3284	Precision Valve Unitized	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3285	Precision Valve Unitized	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3361	Precision Valve System Right	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3362	Precision Valve System Right	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3363	Precision Valve System Right	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3364	Precision Valve System Right	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3365	Precision Valve System Right	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3801	Precision Valve, Right An	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3802	Precision Valve, Right An	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3803	Precision Valve, Right An	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt

Title: DECLARATION OF CONFORMITY – Appendix 2

Number: WI-190003

Revision: 7

CO Number: 103095152

Type: Non PPE

Class: Work Instruction

Release Level: Production

Hydrocephalus Shunt System and Components DD-015 Rev F

PRODUCT CODE	DESCRIPTION	Sterile/Non-Sterile	CE MARK DATE	GMDN CODE	GMDN CODE DESCRIPTION
82-3804	Precision Valve, Right An	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3805	Precision Valve, Right An	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3806	Precision Valve - Very Low	Sterile	Prior to: 21-MAY-2002	45964	Ventriculoperitoneal shunt
82-3807	Precision Valve - Low W/O	Sterile	Prior to: 21-MAY-2002	45964	Ventriculoperitoneal shunt
82-3808	Precision Valve - Medium	Sterile	Prior to: 21-MAY-2002	45964	Ventriculoperitoneal shunt
82-3809	Precision Valve - Medium	Sterile	Prior to: 21-MAY-2002	45964	Ventriculoperitoneal shunt
82-3810	Precision Valve - High W/	Sterile	Prior to: 21-MAY-2002	45964	Ventriculoperitoneal shunt
82-3811	Precision Valve - Very Lo	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3812	Precision Valve - Low S.G	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3813	Precision Valve - Medium	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3814	Precision Valve - Medium	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3815	Precision Valve - High S.	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3816	Precision Valve - Very Lo	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3817	Precision Valve - Low W/O	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3818	Precision Valve - Medium	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3819	Precision Valve - Medium	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3820	Precision Valve - High S.	Sterile	Prior to: 21-MAY-2002	45694	Ventriculoperitoneal shunt
82-3821	Precision Valve - Very Low	Sterile	Prior to: 21-MAY-2002	45964	Ventriculoperitoneal shunt
82-3822	Precision Valve - Low S.G	Sterile	Prior to: 21-MAY-2002	45964	Ventriculoperitoneal shunt
82-3823	Precision Valve - Medium	Sterile	Prior to: 21-MAY-2002	45964	Ventriculoperitoneal shunt
82-3824	Precision Valve - Medium	Sterile	Prior to: 21-MAY-2002	45964	Ventriculoperitoneal shunt
82-3825	Precision Valve - High S.	Sterile	Prior to: 21-MAY-2002	45964	Ventriculoperitoneal shunt
82-3832	CHPV Inline Valve With	Sterile	Prior to: 21-MAY-2002	35965	Ventriculo-peritoneal/atrial shunt valve
82-3834	CHPV Inline Valve Without	Sterile	Prior to: 21-MAY-2002	35965	Ventriculo-peritoneal/atrial shunt valve
82-3838	CHPV Right	Sterile	Prior to:	35965	Ventriculo-

Title: DECLARATION OF CONFORMITY – Appendix 2

Number: WI-190003

Revision: 7

CO Number: 103095152

Type: Non PPE

Class: Work Instruction

Release Level: Production

Hydrocephalus Shunt System and Components DD-015 Rev F

PRODUCT CODE	DESCRIPTION	Sterile/Non-Sterile	CE MARK DATE	GMDN CODE	GMDN CODE DESCRIPTION
	Angle Valve		21-MAY-2002		peritoneal/atrial shunt valve
82-3842	CHPV Inline Valve With Siphonguard	Sterile	Prior to: 21-MAY-2002	35965	Ventriculo-peritoneal/atrial shunt valve
82-3844	CHPV Inline Valve Without	Sterile	Prior to: 21-MAY-2002	35965	Ventriculo-peritoneal/atrial shunt valve
NS5117	Precision Micro Valve System with Unitized Vent & Distal Catheter	Sterile	27-APR-2007	45694	Ventriculoperitoneal shunt
NS5118	Precision Micro Valve System with Unitized Vent & Distal Catheter	Sterile	27-APR-2007	45694	Ventriculoperitoneal shunt
NS5123	Precision Micro Valve System with Unitized Vent & Distal Catheter	Sterile	27-APR-2007	45694	Ventriculoperitoneal shunt