



Declaration of Conformity

Hydrocephalus Products

ET 524, Rev K

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

Full Quality Assurance Certificate CE 00484

MDD Annex II excluding Section 4

Products:

See attached list

Classification: IIb, Rule 8 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

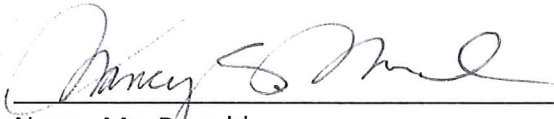
Type: Non PPE

Class: Work Instruction

Release Level: Production

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Start of CE Marking: See Attached



Nancy MacDonald

Manager, Regulatory Affairs

28/09/2017
DD/MM/YYYY



Jocelyn Raposo

Associate Director, Regulatory Affairs

28/09/2017
DD/MM/YYYY

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PRODUCT CODE	DESCRIPTION	Sterile/ Non-Sterile	CE MARK DATE	GMDN CODE	GMDN CODE DESCRIPTION
82-1615	Holter Rickham Reservoir Plastic Base Standard	Sterile	N/A	15974	Cerebrospinal Fluid Reservoir
82-1621	Holter Rickham Reservoir Stainless Steel Base Standard	Sterile	N/A	15974	Cerebrospinal Fluid Reservoir
82-1616	Holter Rickham Reservoir (Large) Plastic Base	Sterile	N/A	15974	Cerebrospinal Fluid Reservoir
82-1623	Holter Rickham Reservoir (Large) Stainless Steel Base	Sterile	N/A	15974	Cerebrospinal Fluid Reservoir
82-1617	Holter Rickham Reservoir (low profile) Plastic Base	Sterile	N/A	15974	Cerebrospinal Fluid Reservoir
82-1625	Holter Rickham Reservoir (low profile) Stainless Steel Base	Sterile	N/A	15974	Cerebrospinal Fluid Reservoir
82-1618	Holter Rickham Reservoir Plastic Base, Small	Sterile	N/A	15974	Cerebrospinal Fluid Reservoir
82-1619	Holter Rickham Reservoir Plastic Base, Large	Sterile	N/A	15974	Cerebrospinal Fluid Reservoir
82-1682	Holter Distal Peritoneal Catheters, Barium, 90 cm, Open-ended	Sterile	N/A	16433	Peritoneal Catheter
82-1684	Holter Distal Peritoneal Catheters, Barium, 90 cm, Salmon Style	Sterile	N/A	16433	Peritoneal Catheter
82-1694	Holter Type A Connector, Stainless Steel, 10.4 mm	Non-Sterile	N/A	47575	Cerebrospinal Fluid Connector
82-1695	Holter Type B Connector, Stainless Steel, 8mm	Non-Sterile	N/A	47575	Cerebrospinal Fluid Connector
82-1697	Holter In-Line Shunt Filter	Sterile	N/A	15688	Hydrocephalic Shunt Filter
Codman ACCU-FLO Products					
82-1301	Accu-Flo Barium Distal Slit Valve 2-5cm, H ₂ O Low Pressure	Sterile	N/A	16433	Peritoneal Catheter
82-1302	Accu-Flo Barium Distal Slit Valve 5-9cm, H ₂ O Medium Pressure	Sterile	N/A	16433	Peritoneal Catheter
82-1303	Accu-Flo Barium Distal Slit Valve 9-14cm, H ₂ O High Pressure	Sterile	N/A	16433	Peritoneal Catheter
82-1380	Accu-Flo Barium Distal Open End Catheter	Sterile	N/A	16433	Peritoneal Catheter
82-6100	Accu-Flo CSF Reservoir, 14mm	Sterile	N/A	15974	Cerebrospinal Fluid Reservoir
82-6101	Accu-Flo CSF Reservoir, 24mm	Sterile	N/A	15974	Cerebrospinal Fluid Reservoir
82-1401	Accu-Flo Reservoir	Sterile	N/A	15974	Cerebrospinal Fluid Reservoir
82-1411	Accu-Flo Reservoir	Sterile	N/A	15974	Cerebrospinal Fluid Reservoir
82-1421	Accu-Flo Reservoir	Sterile	N/A	15974	Cerebrospinal Fluid Reservoir
82-6010	Accu-Flo Burr Hole Button & Cover	Sterile	N/A	15749	Cranial Bur Hole Cover

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82-6025	Accu-Flo Burr Hole Button & Cover	Sterile	N/A	15749	Cranial Bur Hole Cover
82-1501	Accu-Flo Shunt Connector	Sterile	N/A	47575	Cerebrospinal Fluid Connector
82-1504	Accu-Flo Straight Connector	Sterile	N/A	47575	Cerebrospinal Fluid Connector
82-1507	Accu-Flo Straight Connector	Sterile	N/A	47575	Cerebrospinal Fluid Connector
82-1511	Accu-Flo Shunt Connector	Sterile	N/A	47575	Cerebrospinal Fluid Connector
82-1520	Accu-Flo Three Way Connector	Sterile	N/A	47575	Cerebrospinal Fluid Connector
82-1521	Accu-Flo Shunt Connector	Sterile	N/A	47575	Cerebrospinal Fluid Connector
82-3053	Bioplate Shunt Connector (sterile)	Sterile	N/A	47575	Cerebrospinal Fluid Connector
Siphonguard					
82-3090	Siphonguard CSF Control Device	Sterile	N/A	35965	Ventriculo-peritoneal/atrial shunt valve
Codman Hakim Precision and Micro Precision Codman Hakim Programmable and Micro Programmable Valves					
82-3095	Micro Precision With Rickham Reservoir	Sterile	N/A	35965	Hydrocephalic Valve
82-3096	Micro Precision With Rickham Reservoir	Sterile	N/A	35965	Hydrocephalic Valve
82-3097	Micro Precision With Rickham Reservoir	Sterile	N/A	35965	Hydrocephalic Valve
82-3098	Micro Precision With Rickham Reservoir	Sterile	N/A	35965	Hydrocephalic Valve
82-3099	Micro Precision With Rickham Reservoir	Sterile	N/A	35965	Hydrocephalic Valve
82-3162	In-Line with SiphonGuard	Sterile	N/A	35965	Hydrocephalic Valve
82-3164	In-Line	Sterile	N/A	35965	Hydrocephalic Valve
82-3182	Right Angle with SiphonGuard	Sterile	N/A	35965	Hydrocephalic Valve
82-3184	Right Angle	Sterile	N/A	35965	Hydrocephalic Valve
82-3116	Micro programmable Integral Rickham Reservoir	Sterile	N/A	35965	Hydrocephalic Valve
82-5461	In-Line with SiphonGuard	Sterile	N/A	35965	Hydrocephalic Valve
82-5462	In-Line with SiphonGuard	Sterile	N/A	35965	Hydrocephalic Valve

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82-5463	In-Line with SiphonGuard	Sterile	N/A	35965	Hydrocephalic Valve
82-5464	In-Line with SiphonGuard	Sterile	N/A	35965	Hydrocephalic Valve
82-5465	In-Line with SiphonGuard	Sterile	N/A	35965	Hydrocephalic Valve
82-5471	In-Line	Sterile	N/A	35965	Hydrocephalic Valve
82-5472	In-Line	Sterile	N/A	35965	Hydrocephalic Valve
82-5473	In-Line	Sterile	N/A	35965	Hydrocephalic Valve
82-5474	In-Line	Sterile	N/A	35965	Hydrocephalic Valve
82-5475	In-Line	Sterile	N/A	35965	Hydrocephalic Valve
82-5481	Right Angle with SiphonGuard	Sterile	N/A	35965	Hydrocephalic Valve
82-5482	Right Angle with SiphonGuard	Sterile	N/A	35965	Hydrocephalic Valve
82-5483	Right Angle with SiphonGuard	Sterile	N/A	35965	Hydrocephalic Valve
82-5484	Right Angle with SiphonGuard	Sterile	N/A	35965	Hydrocephalic Valve
82-5485	Right Angle with SiphonGuard	Sterile	N/A	35965	Hydrocephalic Valve
82-5491	Right Angle	Sterile	N/A	35965	Hydrocephalic Valve
82-5492	Right Angle	Sterile	N/A	35965	Hydrocephalic Valve
82-5493	Right Angle	Sterile	N/A	35965	Hydrocephalic Valve
82-5494	Right Angle	Sterile	N/A	35965	Hydrocephalic Valve
82-5495	Right Angle	Sterile	N/A	35965	Hydrocephalic Valve
82-3011	Valve and Pre-Chamber only with valve introducer	Sterile	N/A	35965	Hydrocephalic Valve
82-3012	Valve and Pre-Chamber only with valve introducer	Sterile	N/A	35965	Hydrocephalic Valve
82-3013	Valve and Pre-Chamber only with valve introducer	Sterile	N/A	35965	Hydrocephalic Valve
82-3014	Valve and Pre-Chamber only with valve introducer	Sterile	N/A	35965	Hydrocephalic Valve
82-3015	Valve and Pre-Chamber only with valve introducer	Sterile	N/A	35965	Hydrocephalic Valve
82-3026	Micro PrecisionWithout catheters	Sterile	N/A	35965	Hydrocephalic Valve

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82-3027	Micro PrecisionWithout catheters	Sterile	N/A	35965	Hydrocephalic Valve
82-3028	Micro PrecisionWithout catheters	Sterile	N/A	35965	Hydrocephalic Valve
82-3029	Micro PrecisionWithout catheters	Sterile	N/A	35965	Hydrocephalic Valve
82-3030	Micro PrecisionWithout catheters	Sterile	N/A	35965	Hydrocephalic Valve
82-3045	Peritoneal catheter, 85 cm	Sterile	N/A	35965	Hydrocephalic Valve
82-3048	Straight connector, stainless steel	Sterile	N/A	35965	Hydrocephalic Valve
82-3049	Right angle connector, stainless steel	Sterile	N/A	35965	Hydrocephalic Valve
82-3052	Right Angle Adaptor	Sterile	N/A	35965	Hydrocephalic Valve
82-3055	Hakim Valve Introducer	Sterile	N/A	35965	Hydrocephalic Valve
82-3082	Precision Valve Cylin VLow	Sterile	N/A	35965	Hydrocephalic Valve
82-3083	Precision Valve Cylin Low	Sterile	N/A	35965	Hydrocephalic Valve
82-3084	Precision Valve Cylin M Low	Sterile	N/A	35965	Hydrocephalic Valve
82-3085	Precision Valve Cylin M High	Sterile	N/A	35965	Hydrocephalic Valve
82-3086	Precision Valve Cylin High	Sterile	N/A	35965	Hydrocephalic Valve
82-3110	CHPV with prechamber, no catheters	Sterile	N/A	35965	Hydrocephalic Valve
82-3112	Micro Programmable	Sterile	N/A	35965	Hydrocephalic Valve
82-3115	Cylindrical	Sterile	N/A	35965	Hydrocephalic Valve
NS5026	Micro II Precision, Plastic base, unitized Rickham	Sterile	N/A	35965	Hydrocephalic Valve
NS5027	Micro II Precision, Plastic base, unitized Rickham	Sterile	N/A	35965	Hydrocephalic Valve
NS5028	Micro II Precision, Plastic base, unitized Rickham	Sterile	N/A	35965	Hydrocephalic Valve
NS5029	Micro II Precision, Plastic base, unitized Rickham	Sterile	N/A	35965	Hydrocephalic Valve
NS5030	Micro II Precision, Plastic base, unitized Rickham	Sterile	N/A	35965	Hydrocephalic Valve
NS5034	Cylindrical, Programmable, No reservoir, integral connectors both ends	Sterile	N/A	35965	Hydrocephalic Valve

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NS0496	Precision Valve	Sterile	N/A	35965	Hydrocephalic Valve
NS0497	Precision Valve	Sterile	N/A	35965	Hydrocephalic Valve
NS0498	Precision Valve	Sterile	N/A	35965	Hydrocephalic Valve
NS0499	Precision Valve	Sterile	N/A	35965	Hydrocephalic Valve
NS0500	Precision Valve	Sterile	N/A	35965	Hydrocephalic Valve
0148CSD	HAKIM Programmable Micro Valve	Sterile	N/A	35965	Hydrocephalic Valve
Uni-Shunt					
82-8591	Anchoring Clip	Sterile	N/A	47575	Cerebrospinal Fluid Connector