EC Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of the legal manufacturer.

Name of Products:	S&IP Accessories
Product Codes:	See **Attachment A**
UMDNS Code:	N/A
GMDN Code:	56631: Wearable percutaneous catheter/tube holder 31072: Personal device holder, Single Use 37480: General-purpose patient lifting system sling/harness 58128: Limb tourniquet, manual, single-use 64905: Intravenous catheter guard
CND Code:	V80: Clinical Accessories: Not Otherwise Classified
Legal Manufacturer (Place of Issue):	O&M Halyard, Inc. 9120 Lockwood Blvd. Mechanicsville, Virginia (VA) 23116 United States of America
Manufacturer SRN :	N/A
Authorized Representative:	ArcRoyal Virginia Road Kells, Co Meath, Ireland
AR SRN: **Basic UDI-DI: (device level)**	IE-AR-0000003110 06806517SIPA001KE
Start of CE:	12 June 2015

Conformity Assessment Route:	Technical Documentation according to Annex II & III; Declaration of Conformity according to Annex IV of Regulation (EU) 2017/745
Risk Classification, Rules:	Class I NS per Rule 1, Annex VIII Regultion (EU) 2017/745
CE certificate number:	N/A
Notified Body:	BSI-NL
Quality System Certificate:	FM 697013

COMMON SPECIFICATIONS: **NOT APPLICABLE**

STATEMENT: I, the undersigned, hereby declare that the specified medical device(s) meet(s) the applicable provisions of Regulation (EU) 2017/745 concerning Medical Devices.

All supporting documentation that contains proof of compliance to the aforementioned Regulation(s) is retained under the premises of O&M Halyard, Inc. This declaration applies to all devices on the attached product list from the signature date forward.

Authorized Signature:

Angela L. Bunn
Angela L. Bunn (Jul 30, 2022 09:09 EDT)

On behalf of O&M Halyard, Inc

Name: Angela Bunn
Title: Director, Global Regulatory Affairs
Address: O&M Halyard, Inc.
9120 Lockwood Blvd.
Mechanicsville, Virginia (VA) 23116
United States of America

Date: Jul 30, 2022

ATTACHMENT A: Product Codes and Descriptions for S&IP Accessory Products:

Global SKU	Product Description	Basic UDI-DI
29900	HAND-AID* IV Wrist Support, White – Adult	06806517SIPA001KE
29920	Antecubital IV Support	06806517SIPA001KE
29965	IV Support Neonatal, White	06806517SIPA001KE
29967	IV Support Child, White	06806517SIPA001KE
29970	HAND AID* IV Wrist Support, Pediatric	06806517SIPA001KE
29980	HAND-AID* Arterial Wrist Support	06806517SIPA001KE
29985	HAND AID* Arterial Replacement Pad with Straps, Adult	06806517SIPA001KE
36600	Catheter Leg Strap	06806517SIPA001KE
52710	Personal Stirrup Strap	06806517SIPA001KE
52712	Stirrup Strap with Slip Ring	06806517SIPA001KE
53600	OR Tourniquet Cover, Small	06806517SIPA001KE
53605	OR Tourniquet Cover, Large	06806517SIPA001KE
54800	OR Table/Stretcher Strap	06806517SIPA001KE
55299	TS-30* Personal Utility Strap	06806517SIPA001KE
71800	Telemetry Unit Pouch	06806517SIPA001KE

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Final Audit Report 2022-07-30

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