EC Declaration of Conformity

Name of Products:	S&IP Accessories
Product Codes:	See **Attachment A**
UMDNS Code:	N/A
GMDN Code:	35497: Tube, Holder, Catheter 31072: Bag, Medical Device, Single Use 40535: Lift, Patient Transfer, Sling/Harness/Strap 15571: Covers
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: **UDI-DI: (device level)**	N/A 06806517SIPA001KE
Start of CE:	4 November 2020
Conformity Assessment Route:	Annex VIII 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

O&M Halyard, Inc.
5405 Windward Parkway
Alpharetta, Georgia 30004

1-844-HALYARD

halyardhealth.com

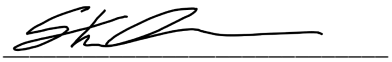
Notified Body:	BSI-NL
Quality System Certificate:	FM 697013

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:



On behalf of O&M Halyard, Inc

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

Date: 11 December 2020

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

Global SKU	Product Description	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
29985	HAND AID* Arterial Replacement, Adult	06806517SIPA001KE
36600	Soft Circumcision	06806517SIPA001KE
52712	Stirrup Strap with Slip Ring	06806517SIPA001KE
53600	OR Tourniquet Cover, Small	06806517SIPA001KE
53605	OR Tourniquet Cover, Large	06806517SIPA001KE
71800	Telemetry Unit Pouch	06806517SIPA001KE
71900	Telemetry Unit Pouch	06806517SIPA001KE