

	Declaration of Conformity	DoC-056 Revision Number: 106
	S1050: Portex Suction Catheters - Closed Suction	

Manufacturer: Smiths Medical ASD Inc.
 6000 Nathan Lane North
 Minneapolis, Minnesota 55442 USA

EU Representative: Smiths Medical Czech Republic a. s.
 Olomoucká 306,
 Hranice 1 - Město,
 753 01 Hranice, Czech Republic

Product Tradename(s): SuctionPro72™

Product Scope: Sterile Drainage Devices

Conformity Assessment Route: Annex II (excluding Section 4)

Notified Body: BSI Healthcare
 Medical Devices Certification
 Notified Body #2797

EC Certificate Number: CE 669121

Start of CE-Marking: SEP, 2012

We hereby declare that the products listed in Appendix 1 conform with the relevant provisions of Directive 93/42/EEC of June 14, 1993 as transposed into UK law by Statutory Instrument S.I. 2008 No. 2936 and as amended by Directive 2007/47/EC of the European Parliament and of the Council of September 5, 2007 concerning medical devices as transposed into national regulations and by subsequent Directives, laws, and other national regulations. We are hereby exclusively responsible for the contents found on this declaration of conformity. All supporting documentation is retained under the premise of the Manufacturer.

Authorized Signatory:

Signature: Stacy Novak Date: 23 AUG 2019

Name: Stacy Novak

Title: Sr. Manager, Regulatory Operations

Location of Signatory: Minneapolis, MN, USA

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Appendix 1: Product List

Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
1.	Z110-10	SUCTIONPRO72 SL 10	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
2.	Z110-12	SUCTIONPRO72 SL 12	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
3.	Z110-14	SUCTIONPRO72 SL 14	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
4.	Z110-16	SUCTIONPRO72 SL 16	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
5.	Z110N-10	SUCTIONPRO72 SL 10 No 1WVL	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
6.	Z110N-12	SUCTIONPRO72 SL 12 No 1WVL	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
7.	Z110N-14	SUCTIONPRO72 SL 14 No 1WVL	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5

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Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
8.	Z110N-16	SUCTIONPRO72 SL 16 No 1WVL	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
9.	Z115-10	SUCTIONPRO72 SL 10 TR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
10.	Z115-12	SUCTIONPRO72 SL 12 TR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
11.	Z115-14	SUCTIONPRO72 SL 14 TR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
12.	Z115-16	SUCTIONPRO72 SL 16 TR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
13.	Z115N-12	SUCTIONPRO72 SL 12 TR No 1WVL	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
14.	Z115N-14	SUCTIONPRO72 SL 14 TR No 1WVL	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5

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Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
15.	Z116-14	SUCTIONPRO72 SL 14 TR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
16.	Z116N-14	SUCTIONPRO72 SL 14 TR No 1WVL	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
17.	Z118-14	SUCTIONPRO72 SL 14	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
18.	Z118N-12	PORTEX SUCTIONPRO 72 SL 12 WITHOUT 1WVL	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
19.	Z118N-14	SUCTIONPRO72 SL 14 No 1WVL	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
20.	Z118N-16	PORTEX SUCTIONPRO 72 SL 16 WITHOUT 1WVL	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
21.	Z120-10	SUCTIONPRO72 SL 10 COUD	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5

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Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
22.	Z120-12	SUCTIONPRO72 SL 12 COUD	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
23.	Z120-14	SUCTIONPRO72 SL 14 COUD	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
24.	Z120-16	SUCTIONPRO72 SL 16 COUD	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
25.	Z120N-10	PORTEX SUCTIONPRO 72 SL 10 COUDÉ WITHOUT 1WVL	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
26.	Z120N-12	PORTEX SUCTIONPRO 72 SL 12 COUDÉ WITHOUT 1WVL	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
27.	Z120N-14	PORTEX SUCTIONPRO 72 SL 14 COUDÉ WITHOUT 1WVL	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
28.	Z120N-16	PORTEX SUCTIONPRO 72 SL 16 COUDÉ WITHOUT 1WVL	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5

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Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
29.	Z150-10	SUCTIONPRO72 SL DSW 10	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
30.	Z150-12	SUCTIONPRO72 SL DSW12	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
31.	Z150-14	SUCTIONPRO72 SL DSW 14	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
32.	Z150-16	SUCTIONPRO72 SL DSW 16	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
33.	Z150N-14	PORTEX SUCTIONPRO 72 SL 14 DSW WITHOUT 1WVL	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
34.	Z155-10	SUCTIONPRO72 SL DSW 10 TR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
35.	Z155-12	SUCTIONPRO72 SL DSW 12 TR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5

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Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
36.	Z155-14	SUCTIONPRO72 SL DSW 14 TR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
37.	Z155-16	SUCTIONPRO72 SL DSW 16 TR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
38.	Z155N-10	PORTEX SUCTIONPRO 72 SL 10 DSW TR WITHOUT 1WVL	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
39.	Z155N-12	PORTEX SUCTIONPRO 72 SL 12 DSW TR WITHOUT 1WVL	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
40.	Z155N-14	PORTEX SUCTIONPRO 72 SL 14 DSW TR WITHOUT 1WVL	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
41.	Z155N-16	PORTEX SUCTIONPRO 72 SL 16 DSW TR WITHOUT 1WVL	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
42.	Z156-14	SUCTIONPRO72 SL DSW 14 TR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5

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Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
43.	Z160-14	SUCTIONPRO72 SL DSW 14 COUD	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
44.	Z160-16	SUCTIONPRO72 SL DSW 16 COUD	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	34041	Ila	5
45.	Z210-12	SUCTIONPRO72 DL 12	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	32158	Ila	5
46.	Z210-14	SUCTIONPRO72 DL 14	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	32158	Ila	5
47.	Z210-16	SUCTIONPRO72 DL 16	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	32158	Ila	5
48.	Z215-12	SUCTIONPRO72 DL 12 TR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	32158	Ila	5
49.	Z215-14	SUCTIONPRO72 DL 14 TR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	32158	Ila	5

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Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
50.	Z216-14	SUCTIONPRO72 DL 14 TR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	32158	Ila	5
51.	Z250-12	SUCTIONPRO72 DL DSW 12	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	32158	Ila	5
52.	Z250-14	SUCTIONPRO72 DL DSW 14	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	32158	Ila	5
53.	Z250-16	SUCTIONPRO72 DL DSW 16	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	32158	Ila	5
54.	Z255-12	SUCTIONPRO72 DL 12 DSW TR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	32158	Ila	5
55.	Z255-14	SUCTIONPRO72 DL 14 DSW TR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	32158	Ila	5
56.	Z256-14	SUCTIONPRO72 DL DSW 14 TR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	N/A	32158	Ila	5

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Appendix 2: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date (DD-MMM-YYYY Format)
02	Updating to the latest DoC template and updating EC certificate information	Breanna Fautsch	30-NOV-2016
003	Change document number format from SXXX to DoC-XXX to load documents into Agile. No updates made to content of this document with the exception of the document number from S1050 to DoC-056 and revision from 02 to 003 and added STED # to header for traceability to STED.	Stacy Novak	31-MAY-2017
004	The purpose of this revision update was in response to Notified Body Transfer. The Changes to this DoC include: Notified Body name from Intertek to BSI, updated to new certificate number from 053 01 A CE to CE 661325, updated to new revision from 003 to 004 and changed the effective date.	Manasa Boppana	21-AUG-2017
005	Updated DoC to the latest template in Agile from Rev 002 to 003. Updated the STED Name in the header to reflect the name on the STED from Portex Suction Catheters Closed Suction to Portex® Suction Catheters - Closed Suction. Updated the name of the Manufacturer on Page 1 from Smiths Medical International to Smiths Medical International Ltd. to reflect the name on the product certificate. Updated the Manufacturing Site address for Tijuana to match what is on the product certificate.	Mitchell Madsen	22-FEB-2018
106	Updated to the newest template revision (from 003 to 104). Unmerged cells in Appendix 1 for easier reading and editing. Changed revision from 005 to 106 due to revision formatting requirements in DVSOP2005. Changed the legal manufacturer from MHYT to MMSP as per FM-DVSOP8005-05. Added Hranice, Czech Republic as EU Representative. An EU Representative is needed if a product is commercially distributed in the EU and not manufactured in the EU. Since	Brian Merchant/Alicia Wilson	22-AUG-2019

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	the Legal Manufacturer is changing to MMSP, an EU Representative is needed. Changed the Notified Body from BSI UK (0086) to BSI NL (2797) as BSI is migrating issued certificates from the UK to the Netherlands due to Brexit. Changed the EC Certificate from CE 661325 to CE 669121 due to the Legal Manufacturer change. Changed the Product Scope from "Suction Catheters" to "Sterile Drainage Devices" to align with EC Certificate 669121. Revised the Product Descriptions to match the descriptions in Agile. Revised the Tijuana Manufacturing Site address to match the address listed on EC Certificate 669121. Changed the GMDN Code from 34041 to 32158 for SKUs Z210-14, Z210-16, Z215-12, Z215-14, Z216-14, Z250-12, Z250-14, Z255-12, Z255-14 and Z256-14 as the affected SKUs are dual lumen (as opposed to single lumen).		