

	Declaration of Conformity	DoC-147 Revision Number: 110
	S1212: Jelco IntuitIV Safety IV Catheter	

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

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

Product Tradename(s): Jelco IntuitIV Safety IV Catheter™

Conformity Assessment Route: Annex II (excluding Section 4)

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

EC Certificate Number: CE 669121

Smiths Medical ASD, Inc. hereby declares under its sole responsibility that the product(s) referenced conform to the relevant provisions of the European Union Council Directive 93/42/EEC on Medical Devices (the MDD) as amended by Directive 2007/47/EC.

Reference Attachment 1 for list of affected SKUs.

Authorized Signatory:

Signature: Angela Kilian Date: 27 Aug 2020

Name: Angela Kilian

Title: Director, Regulatory Affairs

Location of Signatory: Minneapolis, MN, USA

Controlled Copy – Verify Revision & Effective Date are current before use.

	Declaration of Conformity	DoC-147 Revision Number: 110
	S1212: Jelco IntuitIV Safety IV Catheter	

Appendix 1: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
004	New template. Change document number format from SXXX to DoCXXX to load documents into Agile. No updates made to content of this document with the exception of the document number from S1212 to DoC-147 and revision from 003 to 004 and added STED # to header for traceability to STED.	Callie Frick	21-JUN-2017
005	Updated to the new template from REV 002 to REV 003. Updated to the next revision and changed the effective date, removed the repeated product code 7266-AI from rev 004	Manasa Boppana	04-JAN-2018
106	<p>Changed revision format from "00X" to "1XX" due to update of DVSOP2005 which requires document revisions to be in the "1XX" format; there are no missing revisions for this DoC (i.e. rev 006-rev 105).</p> <p>Administrative update due to Intertek AMTAC (0473) closing its offices effective 30-June-2018. Therefore Smiths Medical transferred certification of the products covered under the STED from Intertek AMTAC #0473 to Intertek SEMKO AB #0413 effective 1-July-2018. Added Intertek SEMKO information to cover product labeled both with Intertek AMTAC and Intertek SEMKO.</p> <p>No technical content review or updates were performed during this revision update.</p>	Izzy Wallstein	10-OCT-2018
107	<p>Updated to the newest template revision (from rev 003 to 104).</p> <p>Removed Intertek AMTAC information from the Notified Body and EC Certificate fields as June 30, 2018 has passed. As of July 1, 2018, SEMKO AB is the Notified Body.</p> <p>Added Smiths Medical Czech Republic a.s. as the EU Representative. An EU Representative is needed if a product is commercially distributed in the EU and is not manufactured in the EU. Since Ashford will no longer be part of the EU, due</p>	Alicia Wilson	12-JUL-2018

	Declaration of Conformity	DoC-147 Revision Number: 110
	S1212: Jelco IntuitIV Safety IV Catheter	

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
	to Brexit, an EU Representative needs to be added to the DoCs. Revised product descriptions to match the descriptions in Agile. For the Smiths Medical Italia S.r.L Manufacturing Site, capitalized the "D" in "Via della Stazione 2" to match the ISO 13485 certificate (MD 516859) for Latina.		
108	Updated template from rev 104 to 105. GMDN Code 40601 was made obsolete by the GMDN Agency. The GMDN Code for all SKUs have been replaced with 64574.	Rosanna Lee	06-DEC-2019
109	Updated DoC to current template (from rev 105 to 107), which includes moving the SKUs from Appendix 1 to Attachment 1. Legal Manufacturer, Notified Body and EC Certificate were updated to reflect Notified Body change from Intertek SEMKO AB to BSI.	Rosanna Lee	08-MAY-2020
110	Updated the risk classification of all SKUs from IIa to IIb as the devices are used to administer medicine.	Janell Colley	See Agile

Catalog Number	Product Description	GMDN Code	EU Risk Class	EU Rule
7114-AI	Jelco Intuitiv Safety – 14g x 45mm (1 3/4") - SP- FEP	64574	IIb	7
7116-AI	Jelco Intuitiv Safety - 16g x 45mm (1 3/4") - SP - FEP	64574	IIb	7
7118-AI	Jelco Intuitiv Safety - 18g x 45mm (1 3/4") - SP - FEP	64574	IIb	7
7119-AI	Jelco Intuitiv Safety - 18g x 32mm (1 1/4") - SP - FEP	64574	IIb	7
7120-AI	Jelco Intuitiv Safety - 20g x 32mm (1 1/4") - SP - FEP	64574	IIb	7
7122-AI	Jelco Intuitiv Safety - 22g x 25mm (1") - SP - FEP	64574	IIb	7
7130-AI	Jelco Intuitiv Safety - 22g x 25mm (1") - FEP	64574	IIb	7
7131-AI	Jelco Intuitiv Safety - 16g x 32mm (1 1/4") - FEP	64574	IIb	7
7132-AI	Jelco Intuitiv Safety - 16g x 45mm (1 3/4") - FEP	64574	IIb	7
7133-AI	Jelco Intuitiv Safety - 24g x 19mm (3/4") - FEP	64574	IIb	7
7134-AI	Jelco Intuitiv Safety- 18g x 45mm (1 3/4") - FEP	64574	IIb	7
7135-AI	Jelco Intuitiv Safety - 18g x 32mm (1 1/4") - FEP	64574	IIb	7
7136-AI	Jelco Intuitiv Safety - 20g x 32mm (1 1/4") - FEP	64574	IIb	7
7137-AI	Jelco Intuitiv Safety - 20g x 25mm (1") - FEP	64574	IIb	7
7138-AI	Jelco Intuitiv Safety - 14g x 32mm (1 1/4") Straight FEP	64574	IIb	7
7139-AI	Jelco Intuitiv Safety - 20g x 45mm (1 3/4") - FEP	64574	IIb	7
7188-AI	Jelco Intuitiv Safety - 14g x 45mm (1 3/4") - FEP	64574	IIb	7
7214-AI	Jelco Intuitiv Safety - 14g x 45mm (1 3/4") - SP - PUR	64574	IIb	7
7216-AI	Jelco Intuitiv Safety - 16g x 45mm (1 3/4") - SP - PUR	64574	IIb	7
7218-AI	Jelco Intuitiv Safety - 18g x 45mm (1 3/4") - SP - PUR	64574	IIb	7
7219-AI	Jelco Intuitiv Safety - 18g x 32mm (1 1/4") - SP - PUR	64574	IIb	7
7220-AI	Jelco Intuitiv Safety - 20g x 32mm (1 1/4") - SP - PUR	64574	IIb	7
7222-AI	Jelco Intuitiv Safety - 22g x 25mm (1") - SP - PUR	64574	IIb	7
7260-AI	Jelco Intuitiv Safety - 22g x 25mm (1") - PUR	64574	IIb	7
7261-AI	Jelco Intuitiv Safety - 16g x 32mm (1 1/4") - PUR	64574	IIb	7
7262-AI	Jelco Intuitiv Safety - 16g x 45mm (1 3/4") - PUR	64574	IIb	7
7263-AI	Jelco Intuitiv Safety - 24g x 19mm (3/4") - PUR	64574	IIb	7
7264-AI	Jelco Intuitiv Safety - 18g x 45mm (1 3/4") - PUR	64574	IIb	7
7265-AI	Jelco Intuitiv Safety - 18g x 32mm (1 1/4") - PUR	64574	IIb	7
7266-AI	Jelco Intuitiv Safety - 20g x 32mm (1 1/4") - PUR	64574	IIb	7
7267-AI	Jelco Intuitiv Safety - 20g x 25mm (1") - PUR	64574	IIb	7
7268-AI	Jelco Intuitiv Safety - 14g x 32mm (1 1/4") - PUR	64574	IIb	7
7269-AI	Jelco Intuitiv Safety - 20g x 45mm (1 3/4") - PUR	64574	IIb	7

Catalog Number	Product Description	GMDN Code	EU Risk Class	EU Rule
7288-AI	Jelco Intuitiv Safety - 14g x 45mm (1 3/4") - PUR	64574	IIb	7