smiths medical bringing technology to life	**Declaration of Conformity** S1222: Jelco, Jelco Plus, Jelco 2, Optiva, Optiva 2 and Optiva W Intravascular Catheters	DoC-153 Revision Number: 113

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):	OPTIVA® IV catheters and Jelco® 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

Appendix 1: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
005	Updating DoC to the Latest Template; Updating CE Cert #; Adding –INT Mod to each code	M. Madsen	25-MAY-2017
006	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 S1222 to DoC-153 and revision from 005 to 006 and added STED # to header for traceability to STED.	Stacy Novak	30-MAY-2017
007	Removed Notified Body address for consistency across all DoCs.	Stacy Novak	05-JUN-2017
008	Updated to the new template from REV 002 to REV 003, updated to the next revision and changed the effective date.	Manasa Boppana	04-JAN-2018
109	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 009-rev 108). 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. Replaced obsolete GMDN 31670 with the applicable GMDN 40601 due to obsolescence notification from GMDN Agency. No technical content review or updates were performed during this revision update.	Izzy Wallstein	10-OCT-2018
110	Updated to the new template from rev 003 to 104. Updated STED title in header from "Conventional IV catheters" to	Alicia Wilson	12-JUL-2019

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
	"Jelco, Jelco Plus, Jelco 2, Optiva, Optiva 2 and Optiva W Intravascular Catheters" to reflect the STED's description in Agile. 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. 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 to Brexit, an EU Representative needs to be added. 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" and changed "Scala" to "Scalo" to match the ISO 13485 certificate (MD 516859) for Latina. Removed -INT SKUs (1014-INT, 1016-INT, 1018-INT, 1019-INT, 1020-INT, 1022-INT, 1114-INT, 1116-INT, 1118-INT, 1119-INT, 1120-INT, 1122-INT, 1124-INT, 4010-INT, 4012-INT, 4013-INT, 4014-INT, 4016-INT, 4018-INT, 4030-INT, 4032-INT, 4033-INT, 4034-INT, 4035-INT, 4036-INT, 4038-INT, 4039-INT, 5060-INT, 5061-INT, 5062-INT, 5063-INT, 5064-INT, 5065-INT, 5066-INT, 5068-INT, 5069-INT, 7060-INT, 7061-INT, 7062-INT, 7063-INT, 7064-INT, 7065-INT, 7066-INT, 7068-INT, 7069-INT, MR14-INT, MR16-INT, MR18-INT, MR19-INT, MR20-INT, MR22-INT), as they have been replaced with the equivalent -AI SKUs. The -INT SKUs are inactive, blocked in the EU, and have not been manufactured since 2016. The first grouping of -INT SKUs are on CR-OBS-10001129, and the remaining SKUs will be added to a CR-OBS in the next phase.		

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
	Removed 1020 and 1014 as they are inactive/post phase out. Since DoCs capture SKUs that are currently manufactured and currently commercially distributed in the EU, post-phase out SKUs are not needed on DoCs.		
111	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
112	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
113	Updated the risk classification of all SKUs from IIa to IIb as the devices are used to administer medicine.	Janell Colley	See Agile