smiths medical bringing technology to life	**Declaration of Conformity** S1222: Jelco®, Jelco® 2, Optiva®, and Optiva® 2, Optiva® W Intravascular Catheters	DoC-153 Revision Number: 115

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 - Mesto, 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 Group The Netherlands B.V. 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 and to the relevant provisions of Article 120 of the Medical Device Regulation (EU) 2017/745 (the MDR).

Reference Appendix 1 for list of affected SKUs.

Authorized Signatory:

Signature: 

Date: 17-APR-2025

Name: Jeffrey Wan

Title: Senior Manager, Regulatory Affairs

Location of Signatory: Minneapolis, MN, USA

Appendix 1: Product List:

No.	Catalog Number	Product Description	GMDN Code	EU Risk Class	EU Rule
1.	1014	OPTIVA*2 14GX45MM	64574	IIb	7
2.	1016	OPTIVA*2 16GX45MM	64574	IIb	7
3.	1018	OPTIVA*2 18GX45MM	64574	IIb	7
4.	1019	OPTIVA*2 18GX32MM	64574	IIb	7
5.	1020	OPTIVA*2 20GX32MM	64574	IIb	7
6.	1022	OPTIVA*2 22GX25MM	64574	IIb	7
7.	1114	OPTIVA*WINGED 14GX45MM	64574	IIb	7
8.	1116	OPTIVA*WINGED 16GX45MM	64574	IIb	7
9.	1118	OPTIVA*WINGED 18GX45MM	64574	IIb	7
10.	1119	OPTIVA*WINGED 18GX32MM	64574	IIb	7
11.	1120	OPTIVA*WINGED 20GX32MM	64574	IIb	7
12.	1122	OPTIVA*WINGED 22GX25MM	64574	IIb	7
13.	1124	OPTIVA*WINGED 24GX19MM	64574	IIb	7
14.	4010	JELCO*CLEAR 22GX25MM	64574	IIb	7
15.	4012	JELCO*CLEAR 16GX50MM	64574	IIb	7
16.	4013	JELCO*CLEAR 24GX19MM	64574	IIb	7

No.	Catalog Number	Product Description	GMDN Code	EU Risk Class	EU Rule
17.	4014	JELCO*CLEAR 18GX45MM	64574	IIb	7
18.	4016	JELCO*CLEAR 20GX32MM	64574	IIb	7
19.	4018	JELCO*CLEAR 14GX50MM	64574	IIb	7
20.	4030	JELCO*RADIOPAQUE 22GX25MM	64574	IIb	7
21.	4032	JELCO*RADIOPAQUE 16GX50MM	64574	IIb	7
22.	4033	JELCO*RADIOPAQUE 24GX19MM	64574	IIb	7
23.	4034	JELCO*RADIOPAQUE 18GX45MM	64574	IIb	7
24.	4035	JELCO*RADIOPAQUE 18GX32MM	64574	IIb	7
25.	4036	JELCO*RADIOPAQUE 20GX32MM	64574	IIb	7
26.	4038	JELCO*RADIOPAQUE 14GX50MM	64574	IIb	7
27.	4039	JELCO*RADIOPAQUE 20GX45MM	64574	IIb	7
28.	5060	OPTIVA* 22GX25MM	64574	IIb	7
29.	5061	OPTIVA* 16GX32MM	64574	IIb	7
30.	5062	OPTIVA* 16GX50MM	64574	IIb	7
31.	5063	OPTIVA* 24GX19MM	64574	IIb	7
32.	5064	OPTIVA* 18GX45MM	64574	IIb	7
33.	5065	OPTIVA* 18GX32MM	64574	IIb	7

No.	Catalog Number	Product Description	GMDN Code	EU Risk Class	EU Rule
34.	5066	OPTIVA* 20GX32MM	64574	IIb	7
35.	5068	OPTIVA* 14GX50MM	64574	IIb	7
36.	5069	OPTIVA* 20GX45MM	64574	IIb	7
37.	MR14	JELCO*2 14GX45MM	64574	IIb	7
38.	MR16	JELCO*2 16GX45MM	64574	IIb	7
39.	MR18	JELCO*2 18GX45MM	64574	IIb	7
40.	MR19	JELCO*2 19GX32MM	64574	IIb	7
41.	MR20	JELCO*2 20GX32MM	64574	IIb	7
42.	MR22	JELCO*2 22GX25MM	64574	IIb	7

Appendix 2: 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

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
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 “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,	Alicia Wilson	12-JUL-2019

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
	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. 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	27-AUG-2020
114	Updated to current DoC template (from rev 107 to 108), which includes moving the SKUs from Attachment 1 to Appendix 1.	Janell Colley	21-SEP-2021
115	Updated to current DoC template (from rev 108 to 109). Update to Notified Body name. Removed Suffix -AI from all SKUs as they are for only internal references. Removed reference to Jelco Plus as they are not within the scope of this DoC. 7060, 7061, 7062, 7063, 7064, 7065, 7066, 7067, 7068, 7069 SKUs are removed based on their non-transition to MDR and removal of CE marking per Chiswick project (CMP B10008534).	Akash Gouli	See Agile