



DECLARATION OF CONFORMITY WITH MEDICAL DEVICE REGULATION (EU) 2017/745

DoC Number: MDR-DoC-0079

EC Certificate Number: MDR 720725

This declaration is hereby made under the sole responsibility of the legal manufacturer. Medical Devices covered by this declaration comply with the provisions of:

- Medical Device Regulation (EU) 2017/745

NOTIFIED BODY

The BSI Group The Netherlands B.V. has been appointed to undertake activities pursuant to Annex IX of Medical Device Regulation (EU) 2017/745 in respect of all devices except those Class I devices supplied non-sterile and which do not have a measuring function.

REFERENCED STANDARDS/NORMATIVE DOCUMENTS/COMMON SPECIFICATIONS

Medical Device / Quality System	EN ISO 13485:2016+AC:2018+ A11:2021	EN ISO 20417:2021	EN ISO 15223-1:2021
	EN ISO 14971:2019+A11:2021		
General Safety / General Electrical	EN 60601-1:2006/A1:2013	EN 62366-1:2015+A1:2020	
Cleaning, Re-processing, Sterilization, Disinfection and Sterile Device Packaging Standards	EN ISO 17664-1:2021	EN ISO 11138-3:2017	EN ISO 11607-1:2020
	EN ISO 11737-1:2018+A1:2021	EN ISO 17665:2024	EN ISO 11135:2014+A1:2019
Radiation Therapy	EN 60601-2-17:2015		
Patient Contact Standards	EN ISO 10993-1:2020	EN ISO 10993-2:2022	EN ISO 10993-5:2009
	EN ISO 10993-3:2014	EN ISO 10993-10:2023	EN ISO 10993-11:2018
	EN ISO 10993-12:2021	EN ISO 10993-17:2023	EN ISO 10993-18:2020/AMD 1:2023
	EN ISO 10993-23:2021	EN ISO 10993-7:2008+AC:2009+A1:2022	

PRODUCT/PRODUCT GROUP

Intraluminal Applicator Set (See Appendix A for list of part numbers)

Basic UDI-DI: 089947500201093QB, 089947500201060PU, 089947500201020PG, 089947500201102PK

INTENDED USE

The Intraluminal Applicator Set is intended for intraluminal brachytherapy treatments including endobronchial treatments and treatments on body sites such as the esophagus and the bile duct using HDR brachytherapy.

CLASSIFICATION

(EU) 2017/745 Annex VIII Device Classification: Class IIa, Rule 5

CND: Z11010380; BRACHYTHERAPY SYSTEMS - HARDWARE

GMDN: 38436 General-purpose brachytherapy system applicator, remote-afterloading

INTERNATIONAL SUBMISSIONS DOSSIER (TECHNICAL FILE REFERENCE)

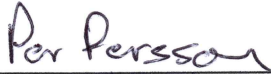
ISD: MDR-ISD-0012 Intraluminal Applicator Set

LEGAL MANUFACTURER

Varian Medical Systems, Inc.
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SRN: US-MF-000001784
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AUTHORIZED REPRESENTATIVE

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Signature

Name: Per Persson

Title: VP RA/QA

Date: 27 November 2024

Place: Crawley, UK

Appendix A:

Devices:

Product Number	Description
GM11000620	Intraluminal Applicator Set

Required Accessories for BRAVOS Afterloader System:

Product Number	Description
GM11009540	Clamping adapter for 5 Fr bronchial catheter, BRAVOS

Required Accessories for GammaMed*plus* Series:

Product Number	Description
GM11000470	Clamping adapter for 5 Fr. bronchial catheter, GammaMed <i>plus</i>
GM11000160	Length cutting gauge for 5 Fr. bronchial catheter, GammaMed <i>plus</i>

Optional Components:

Product Number	Description
GM11003070	Guide tube, Ø 4.5 mm, length 700 mm, front open
GM11000390	Tube catheter, Ø 2.8 mm, GammaMed <i>plus</i>
GM11009760	Tube catheter, Ø 2.8 mm, length 1500 mm, BRAVOS

Kits:

Product Number	Description
GM11000532	Bronchial catheter 5 Fr, sterile, pack of 5
GM11000533	Bronchial catheter 5 Fr, sterile, pack of 10
GM11003182	Guide tube Ø 2.8 mm, length 900 mm, front open, pack of 5
GM11006272	Monofil, Ø 0.8 mm, for bronchial catheter, sterile, pack of 5
GM11003072	Guide tube, Ø 4.5 mm, length 700 mm, front open, pack of 5