



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

DoC Number: MDR-DoC-0060

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	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 11138-7:2019
	EN ISO 11737-2:2020	EN ISO 17665-1:2006	
Radiation Therapy	EN 60601-2-17:2015		
Patient Contact Standards	EN ISO 10993-1:2020	EN ISO 10993-2:2022	EN ISO 10993-3:2014
	EN ISO 10993-5:2009	EN ISO 10993-6:2016	EN ISO 10993-10:2023
	EN ISO 10993-11:2018	EN ISO 10993-12:2021	EN ISO 10993-17:2009
	EN ISO 10993-18:2020	EN ISO 10993-23:2021	

### PRODUCT/PRODUCT GROUP

Interstitial Plastic Needles MR Safe (See Appendix A for list of part numbers)

Basic UDI-DI: 089947500201048Q6 (Plastic needles MR safe); 089947500201040PN (Mandrin)

### INTENDED USE

The Interstitial Plastic Needles MR Safe are intended for use when performing HDR or PDR brachytherapy.

**CLASSIFICATION**

(EU) 2017/745 Annex VIII Device Classification: Class IIa, Rule 7

CND: Z11010380; Brachytherapy systems - Hardware

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

**INTERNATIONAL SUBMISSIONS DOSSIER (TECHNICAL FILE REFERENCE)**

ISD: MDR-ISD- 0015 Interstitial Plastic Needles MR Safe

**LEGAL MANUFACTURER**

Varian Medical Systems, Inc.

3100 Hansen Way

Palo Alto, CA 94304, USA

SRN: US-MF-000001784

customer.relations@varian.com

**AUTHORIZED REPRESENTATIVE**

Varian Medical Systems Nederland B.V.

Kokermolen 2

3994 DH Houten, The Netherlands

SRN: NL-AR-000000803



*Signature*

Name: Per Persson

Date: August 21, 2024

Title: VP RA/QA

Place: Crawley, UK

## Appendix A:

Product Number	Description
GM11014700	Plastic needle MR safe, 2.0 mm diameter x 113 mm length, with mandrin (GM11010390)
GM11014702	Plastic needle MR safe, 2.0 mm diameter x 113 mm length, with mandrin (GM11010390), pack of 10
GM11014710	Plastic needle MR safe, 2.0 mm diameter x 200 mm length, with mandrin (GM11010450)
GM11014712	Plastic needle MR safe, 2.0 mm diameter x 200 mm length, with mandrin (GM11010450), pack of 10
GM11014713	Plastic needle MR safe, 2.0 mm diameter x 200 mm length, with mandrin (GM11010450), pack of 20
GM11014720	Plastic needle MR safe, 2.0 mm diameter x 320 mm length, with mandrin (GM11010470)
GM11014722	Plastic needle MR safe, 2.0 mm diameter x 320 mm length, with mandrin (GM11010470), pack of 10
GM11014723	Plastic needle MR safe, 2.0 mm diameter x 320 mm length, with mandrin (GM11010470), pack of 20
GM11014724	Plastic needle MR safe, 2.0 mm diameter x 320 mm length, with mandrin (GM11010470), pack of 50
GM11014730	Plastic needle MR safe, 2.0 mm diameter x 320 mm length, blunt tip, with mandrin (GM11010470)
GM11014732	Plastic needle MR safe, 2.0 mm diameter x 320 mm length, blunt tip, with mandrin (GM11010470), pack of 10
GM11014733	Plastic needle MR safe, 2.0 mm diameter x 320 mm length, blunt tip, with mandrin (GM11010470), pack of 20
GM11010390	Mandrin for 113mm length
GM11010450	Mandrin for 200mm length
GM11010452	Mandrin for 200 mm length, pack of 10
GM11010470	Mandrin for 320mm length
GM11010472	Mandrin for 320 mm length, pack of 10