TERUMO

No.DOC-DQ010-0800

Rev.10

DECLARATION OF CONFORMITY

We, TERUMO CORPORATION
44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan

being the manufacturer of:

RADIFOCUS Glidewire Advantage

Guide Wire

Product : Catheter Guide Wire

declare that the above products of **Class IIa** are in conformity with the provisions of the EC Council Directive 93/42/EEC of 14 June 1993, as amended, concerning medical devices, and have been subject to the conformity assessment procedure laid down in Article 11, 2 and 11, 3(a) of the Directive, relating to the "Full quality assurance" set out in Annex II, and by certification of Annex II, excluding Section 4 under the supervision of TÜV Rheinland LGA Products GmbH (Registration No.: HD 60145252 0001), Tillystraße 2, 90431 Nürnberg Germany, as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0197.

Authorized European Representative :
TERUMO EUROPE N.V.
Interleuvenlaan 40, 3001 Leuven, Belgium

Object of the declaration : see appendix A

Tokyo, February 10, 2020
(place and date of issue)

Toshio Nakashima
General Manager
Quality Assurance Department
TERUMO CORPORATION

Digitally signed by Grabazei Alexandru
Date: 2020.04.09 13:36:09 EEST
Reason: MoldSign Signature
Location: Moldova

Appendix A －List of Code Number Structure

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1 2 3 4 5 6 7 8 9 10 11 12

Character number	Character & Meaning	
1,2	Product name	RA : Radifocus Glidewire Advantage
3	Destination	＊ : export
4	Specifications of core wire	B : (distal) Ni-Ti/HALF STIFF ＋ (proximal)Ni-Ti C : (distal)Ni-Ti/STIFF ＋ (proximal)Ni-Ti F : (distal) Tip coil marker / Ni-Ti/STIFF ＋ (proximal)Ni-Ti G : (distal)Tip coil marker /Ni-Ti/STIFF ＋ (proximal) Stainless Steel
5	Tip configuration	A : angled type B : angled type S : straight type
6,7	O.D. of product	35 : φ0.89mm(0.035”) 18 : φ0.46mm(0.018”) 14 : φ0.36mm(0.014”)
8,9	Overall length	18 : 180cm 26 : 260cm 30 : 300cm
10	Length of flexible portion at distal end	1 : 1cm 3 : 3cm 5 : 5cm
11	Length of hydrophilic coating	C : 25cm 3 : 30cm
12	Language for labeling	(blank): export M7 M: export M26