

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

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 : $\phi 0.89\text{mm}(0.035")$ 18 : $\phi 0.46\text{mm}(0.018")$ 14 : $\phi 0.36\text{mm}(0.014")$
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