



No.DOC-DC-0138463
Rev.18

DECLARATION OF CONFORMITY

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

being the manufacturer of:

RADIFOCUS Guide Wire GT
With Gold Coil

Product : Catheter Guide Wire

declare that the above products of **Class III** 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, 1(a) of the Directive, relating to the "Full quality assurance" set out in Annex II, and by certification of Annex II, excluding Section 4 (Registration No.: HD 60145252 0001), and Annex II, Section 4 (Registration No.: ID 60156558 0001) under the supervision of TÜV Rheinland LGA Products GmbH, 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, 2024-09-03
(place and date of issue)

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署名時刻: 2024-09-03 | 8:42:03 午前 JST

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Hiroki Sasagawa
General Manager
Quality Assurance Department
TERUMO CORPORATION



Appendix A - List of Code Number Structure

R G * □ □ □ □ □ □ □ □ □ □
1 2 3 4 5 6 7 8 9 10 11 12

Character number	Characters	Meaning
1-2	Product name	RG : RADIFOCUS GUIDE WIRE GT
3	Destination	*: for export
4	Type	G : Non-shapeable type
5	Tip shape	A : 45°angled, B : 70°angled, C : 3.0mm J-angled, E : 90°angled, J : 1.5mm J-angled, K : Double-angled (110°+160°), Q : 15°angled, V : Double-angled (90°+90°), W : Double-angled (90°+ 150°), X : Double-angled (135°+150°)
6-7	Outer diameter of guide wire	Character : 12 14 16 Diameter in inch/ : 0.012” /0.30mm 0.014” /0.36mm 0.016” /0.41mm
8-9	Guide wire length	Characters : 15 , 18 , 20 Length(cm) : 150, 180, 200
10	Flexibility	Characters : S 、 F Type : S: Standard、 F: Floppy
11	Angled tip length	Character : H , J , K , L , N , P , R , None (Standard) Angled tip length(mm) : 2, 3, 5, 6, 7, 8, 9, 4 For products of 4 mm and of other than 2, 3, 5, 6, 7, 8 and 9 mm in angled tip length the eleventh character indicate the language for labeling.
12	Languages used for the indications	Character : M Meaning : Multilanguage

* The characters in front of J-angle are an angle radius.