

DECLARATION OF CONFORMITY

We, **TERUMO EUROPE N.V.**
Interleuvenlaan 40,
3001 Leuven, Belgium

being the manufacturer of:

Kaname™

Cobalt-Chromium Coronary Stent System

Product: Balloon-expandable, coronary artery stent
(See Appendix for related product codes)

declare that the above product of Class III is in conformity with the provisions of the EC Council Directive 93/42/EEC, as amended, concerning medical devices, and has been subject to the conformity assessment procedure laid down in Article 11.1 (a) of the Directive, relating to the “Full Quality Assurance System” set out in Annex II, and by certification of Annex II (Certification No: 3479GB410091103) and Annex II, section. 4 (Certification No: 12920GB411091103), under the supervision of MedCert Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH, Hamburg, Germany as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0482.

Leuven, 02/07/2010

(place and date of issue)



M.J. Aerts
Manager Regulatory Affairs
TERUMO EUROPE N.V.

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3001 Leuven, Belgium

Kaname™

Cobalt-Chromium Coronary Stent System

RELATED ITEM CODES:

Product Code	Expanded Nominal Stent Length	Expanded Nominal Inner Stent Diameter
	mm	mm
CS-RD2509KW	9	2,5
CS-RD2512KW	12	2,5
CS-RD2515KW	15	2,5
CS-RD2518KW	18	2,5
CS-RD2524KW	24	2,5
CS-RD2528KW	28	2,5
CS-RD2709KW	9	2,75
CS-RD2712KW	12	2,75
CS-RD2715KW	15	2,75
CS-RD2718KW	18	2,75
CS-RD2724KW	24	2,75
CS-RD2728KW	28	2,75
CS-RD3009KW	9	3,0
CS-RD3012KW	12	3,0
CS-RD3015KW	15	3,0
CS-RD3018KW	18	3,0
CS-RD3024KW	24	3,0
CS-RD3028KW	28	3,0

Product Code	Expanded Nominal Stent Length	Expanded Nominal Inner Stent Diameter
	mm	mm
CS-RD3509KW	9	3,5
CS-RD3512KW	12	3,5
CS-RD3515KW	15	3,5
CS-RD3518KW	18	3,5
CS-RD3524KW	24	3,5
CS-RD3528KW	28	3,5
CS-RD4009KW	9	4,0
CS-RD4012KW	12	4,0
CS-RD4015KW	15	4,0
CS-RD4018KW	18	4,0
CS-RD4024KW	24	4,0
CS-RD4028KW	28	4,0