

# DECLARATION OF CONFORMITY

We, **TERUMO EUROPE N.V.**  
**Researchpark Zone 2 Haasrode, Interleuvenlaan 40,**  
**3001 Leuven, Belgium**

being the manufacturer of:

## **Nobori®** **DRUG ELUTING STENT SYSTEM**

**Product: Balloon-expandable, coronary artery stent, drug-eluting**

declare that the above product of Class III, incorporating a medicinal substance with ancillary action to the device, is in conformity with the provisions of the EC Council Directive 93/42/EEC of 14 June 1993 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: 3479GB410080116) and Annex II, section. 4 (Certification No: 12340GB411080116), 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, 07 October 2008

(place and date of issue)



Michel Brasseur, PhD

Management Representative

TERUMO EUROPE N.V.





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## **Nobori®** **DRUG ELUTING STENT SYSTEM**

### RELATED ITEM CODES:

Product Code	Expanded stent nominal length	Expanded stent nominal inner diameter
	mm	mm
DE-RA2508SM	8	2.5
DE-RA2514SM	14	2.5
DE-RA2518SM	18	2.5
DE-RA2524SM	24	2.5
DE-RA2528SM	28	2.5
DE-RA3008SM	8	3.0
DE-RA3014SM	14	3.0
DE-RA3018SM	18	3.0
DE-RA3024SM	24	3.0
DE-RA3028SM	28	3.0
DE-RA3508LM	8	3.5
DE-RA3514LM	14	3.5
DE-RA3518LM	18	3.5
DE-RA3524LM	24	3.5
DE-RA3528LM	28	3.5

