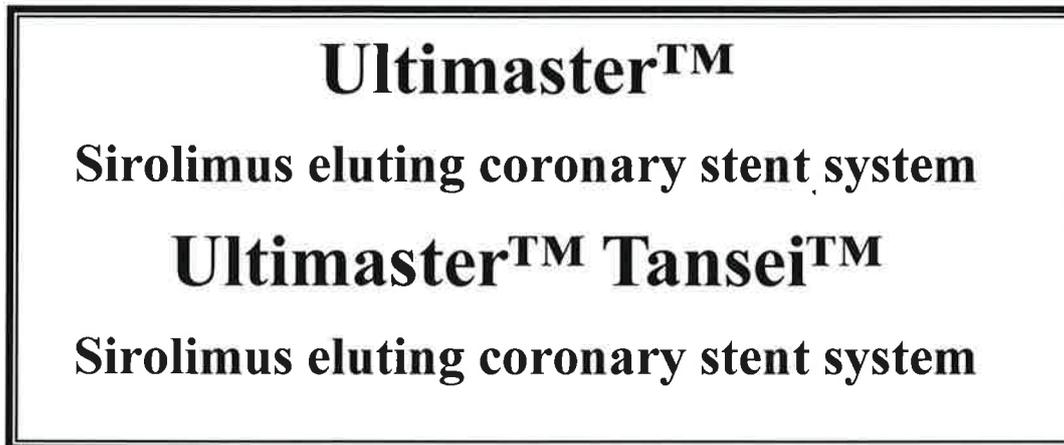


# DECLARATION OF CONFORMITY

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

being the manufacturer of:



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

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 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: 3479GB410191217) and Annex II, section. 4 (Certification No: 13090GB411200504), under the supervision of DNV MEDCERT GmbH, Hamburg, Germany as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0482.

Leuven, 02.12.2022

\_\_\_\_\_  
(place and date of issue)

  
\_\_\_\_\_  
K. Verhaert  
Vice President Quality, Regulatory and Vigilance  
TERUMO EUROPE N.V.

# DECLARATION OF CONFORMITY

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

## Ultimaster™ Sirolimus eluting coronary stent system

### RELATED ITEM CODES:

Product Code	Non-expanded nominal stent length	Nominal expanded stent inner diameter
	mm	mm
DE-RD2209KSM	9	2.25
DE-RD2212KSM	12	2.25
DE-RD2215KSM	15	2.25
DE-RD2218KSM	18	2.25
DE-RD2224KSM	24	2.25
DE-RD2228KSM	28	2.25
DE-RD2233KSM	33	2.25
DE-RD2238KSM	38	2.25
DE-RD2509KSM	9	2.5
DE-RD2512KSM	12	2.5
DE-RD2515KSM	15	2.5
DE-RD2518KSM	18	2.5
DE-RD2524KSM	24	2.5
DE-RD2528KSM	28	2.5
DE-RD2533KSM	33	2.5
DE-RD2538KSM	38	2.5
DE-RD2709KSM	9	2.75
DE-RD2712KSM	12	2.75
DE-RD2715KSM	15	2.75
DE-RD2718KSM	18	2.75
DE-RD2724KSM	24	2.75
DE-RD2728KSM	28	2.75
DE-RD2733KSM	33	2.75
DE-RD2738KSM	38	2.75

Product Code	Non-expanded nominal stent length	Nominal expanded stent inner diameter
	mm	mm
DE-RD3009KSM	9	3.0
DE-RD3012KSM	12	3.0
DE-RD3015KSM	15	3.0
DE-RD3018KSM	18	3.0
DE-RD3024KSM	24	3.0
DE-RD3028KSM	28	3.0
DE-RD3033KSM	33	3.0
DE-RD3038KSM	38	3.0
DE-RD3509KSM	9	3.5
DE-RD3512KSM	12	3.5
DE-RD3515KSM	15	3.5
DE-RD3518KSM	18	3.5
DE-RD3524KSM	24	3.5
DE-RD3528KSM	28	3.5
DE-RD3533KSM	33	3.5
DE-RD3538KSM	38	3.5
DE-RD4009KSM	9	4.0
DE-RD4012KSM	12	4.0
DE-RD4015KSM	15	4.0
DE-RD4018KSM	18	4.0
DE-RD4024KSM	24	4.0
DE-RD4028KSM	28	4.0
DE-RD4033KSM	33	4.0
DE-RD4038KSM	38	4.0

# DECLARATION OF CONFORMITY

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

## Ultimaster™ Tansei™ Sirolimus eluting coronary stent system

**RELATED ITEM CODES:**

Product Code	Non-expanded nominal stent length	Nominal expanded stent inner diameter
	mm	mm
DE-RQ2209KSM	9	2.25
DE-RQ2212KSM	12	2.25
DE-RQ2215KSM	15	2.25
DE-RQ2218KSM	18	2.25
DE-RQ2221KSM	21	2.25
DE-RQ2224KSM	24	2.25
DE-RQ2228KSM	28	2.25
DE-RQ2233KSM	33	2.25
DE-RQ2238KSM	38	2.25
DE-RQ2509KSM	9	2.5
DE-RQ2512KSM	12	2.5
DE-RQ2515KSM	15	2.5
DE-RQ2518KSM	18	2.5
DE-RQ2521KSM	21	2.5
DE-RQ2524KSM	24	2.5
DE-RQ2528KSM	28	2.5
DE-RQ2533KSM	33	2.5
DE-RQ2538KSM	38	2.5
DE-RQ2709KSM	9	2.75
DE-RQ2712KSM	12	2.75
DE-RQ2715KSM	15	2.75
DE-RQ2718KSM	18	2.75
DE-RQ2721KSM	21	2.75
DE-RQ2724KSM	24	2.75
DE-RQ2728KSM	28	2.75
DE-RQ2733KSM	33	2.75
DE-RQ2738KSM	38	2.75

Product Code	Non-expanded nominal stent length	Nominal expanded stent inner diameter
	mm	mm
DE-RQ3009KSM	9	3.0
DE-RQ3012KSM	12	3.0
DE-RQ3015KSM	15	3.0
DE-RQ3018KSM	18	3.0
DE-RQ3021KSM	21	3.0
DE-RQ3024KSM	24	3.0
DE-RQ3028KSM	28	3.0
DE-RQ3033KSM	33	3.0
DE-RQ3038KSM	38	3.0
DE-RQ3509KSM	9	3.5
DE-RQ3512KSM	12	3.5
DE-RQ3515KSM	15	3.5
DE-RQ3518KSM	18	3.5
DE-RQ3521KSM	21	3.5
DE-RQ3524KSM	24	3.5
DE-RQ3528KSM	28	3.5
DE-RQ3533KSM	33	3.5
DE-RQ3538KSM	38	3.5
DE-RQ4009KSM	9	4.0
DE-RQ4012KSM	12	4.0
DE-RQ4015KSM	15	4.0
DE-RQ4018KSM	18	4.0
DE-RQ4021KSM	21	4.0
DE-RQ4024KSM	24	4.0
DE-RQ4028KSM	28	4.0
DE-RQ4033KSM	33	4.0
DE-RQ4038KSM	38	4.0

