

Ultimaster™ Tansei™

Sirolimus Eluting Coronary Stent System

Ultimaster™ Tansei™ Sirolimus Eluting Coronary Stent System is indicated for improving myocardial blood flow in patients with stenotic lesions in coronary arteries, including but not limited to patients with STEMI, NSTEMI, acute coronary syndrome, diabetes mellitus, multivessel disease, bifurcation lesions, patients older than 65 years, male and female patients, patients with totally occluded lesions, long lesions, lesions residing in small coronary vessels, restenotic lesions including in-stent restenosis, ostial lesions, lesions in left main coronary artery. The Ultimaster™ Tansei™ stent system is suitable for both femoral and radial approach.¹

Ultimaster™ Tansei™ provides enhanced pushability² and excellent kink resistance² with a stainless steel tapered core wire at the exit port and advanced shaft technology. With this new DES Terumo introduces a durable yet flexible tip² specially developed for complex stenting procedures. This innovation will improve the deliverability² of the whole stent system versus leading stent delivery systems. Building on the heritage of Ultimaster™ with its proven clinical performance³, Ultimaster™ Tansei™ utilises the same abluminal gradient bioresorbable polymer coating to support early vascular repair and potentially shortened DAPT time.

Product Characteristics

- **2-link, bio-inspired stent design**

Enables stent conformability allowing adaptation to natural vessel shape⁴

Facilitates side-branch access and enables optimal coverage of the bifurcation⁵ thanks to its uniform scaffolding.

- **Advanced abluminal bioresorbable coating:**

Polymer coating is only on the abluminal side of the stent for efficient and targeted drug delivery⁶

Drug coating applied in a gradient to reduce the risk of polymer cracking and delamination, even when the stent is overexpanded⁷

PCL added to PLLA, increasing the elasticity of the bioresorbable polymer coating

- **Simultaneous polymer resorption and drug release**

within 3–4 months¹, to match the procedure-triggered biological response

- **Ultimaster™ Tansei™ facilitates enhanced deliverability²**

Stronger hypotube and stainless steel tapered core wire for enhanced pushability and excellent kink resistance⁶

A durable yet flexible tip supports navigation through tortuous vessels while reducing the risk of tip damage when navigating challenging anatomy⁶

1 Ultimaster Tansei Instructions for Use, version 01-2018

2 Bench test ISCD-523-31-18. Performed by, and data on file at, Terumo Corporation

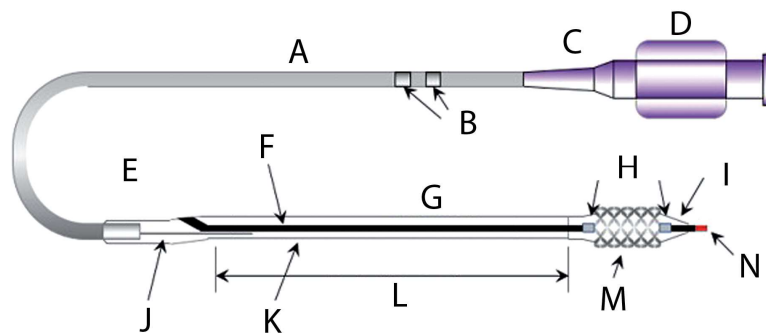
3 Saito S et al. Eur Heart J 2014; 35:2021-2031 and Wijns W et al. Eurointervention 2018;14:343-351

4 Bench test ISCD-523-31-35, data on file at Terumo Corporation

5 Bench test ISCD-523-31-34, data on file at Terumo Corporation

6 Barbato E et al. EuroIntervention 2015;11:541-8

7 Saito N et al. Med Devices 2016;9:33-43



A Proximal shaft
B Depth marker
C Strain relief
D Hub
E Middle shaft

F Inner lumen proximal shaft
G Distal shaft
H PT markers
I Balloon
J Core wire

K Outer lumen Distal shaft
L Hydrophilic Coating
M Drug-Eluting Stent
N Inner lumen Distal shaft

General specifications

Balloon Material	Nylon 12
Coating	Hydrophilic - Distal Shaft
Drug	Sirolimus
Drug Dose Per mm stent length	3.9 µg
Entry Profile	0.018 in / 0.45 mm
Guidewire Compatibility - Diameter	0.014 in / 0.36 mm
Minimum Guide Catheter	0.056 in / 1.42 mm / 5 Fr
Norminal Pressure	9 atm
Polymer	Poly (DL-lactide-co-caprolactone)
Polymer Degradation Time And Drug Release	3 to 4 Months
Shaft - Maximum Size (distal)	0.89 mm / 2.7 Fr
Shaft - Minimum Size (proximal)	0.64 mm / 1.9 Fr
Stent Coating	Abluminal & Gradient
Stent Design	Open Cell
Stent Material	Cobalt Chromium L605
Strut Thickness	80 µm
Usable Length	144 cm

Item specifications

Diameter	Length	Rated Burst Pressure	Code
2.25 mm	9 mm	16 atm	DE-RQ2209KSM
2.25 mm	12 mm	16 atm	DE-RQ2212KSM
2.25 mm	15 mm	16 atm	DE-RQ2215KSM
2.25 mm	18 mm	16 atm	DE-RQ2218KSM
2.25 mm	21 mm	16 atm	DE-RQ2221KSM
2.25 mm	24 mm	16 atm	DE-RQ2224KSM
2.25 mm	28 mm	16 atm	DE-RQ2228KSM
2.25 mm	33 mm	16 atm	DE-RQ2233KSM
2.25 mm	38 mm	16 atm	DE-RQ2238KSM
2.5 mm	9 mm	16 atm	DE-RQ2509KSM
2.5 mm	12 mm	16 atm	DE-RQ2512KSM
2.5 mm	15 mm	16 atm	DE-RQ2515KSM
2.5 mm	18 mm	16 atm	DE-RQ2518KSM
2.5 mm	21 mm	16 atm	DE-RQ2521KSM
2.5 mm	24 mm	16 atm	DE-RQ2524KSM
2.5 mm	28 mm	16 atm	DE-RQ2528KSM
2.5 mm	33 mm	16 atm	DE-RQ2533KSM
2.5 mm	38 mm	16 atm	DE-RQ2538KSM
2.75 mm	9 mm	16 atm	DE-RQ2709KSM
2.75 mm	12 mm	16 atm	DE-RQ2712KSM
2.75 mm	15 mm	16 atm	DE-RQ2715KSM
2.75 mm	18 mm	16 atm	DE-RQ2718KSM
2.75 mm	21 mm	16 atm	DE-RQ2721KSM
2.75 mm	24 mm	16 atm	DE-RQ2724KSM
2.75 mm	28 mm	16 atm	DE-RQ2728KSM
2.75 mm	33 mm	16 atm	DE-RQ2733KSM
2.75 mm	38 mm	16 atm	DE-RQ2738KSM
3.0 mm	9 mm	16 atm	DE-RQ3009KSM
3.0 mm	12 mm	16 atm	DE-RQ3012KSM
3.0 mm	15 mm	16 atm	DE-RQ3015KSM
3.0 mm	18 mm	16 atm	DE-RQ3018KSM
3.0 mm	21 mm	16 atm	DE-RQ3021KSM
3.0 mm	24 mm	16 atm	DE-RQ3024KSM
3.0 mm	28 mm	16 atm	DE-RQ3028KSM
3.0 mm	33 mm	16 atm	DE-RQ3033KSM
3.0 mm	38 mm	16 atm	DE-RQ3038KSM
3.5 mm	9 mm	14 atm	DE-RQ3509KSM
3.5 mm	12 mm	14 atm	DE-RQ3512KSM
3.5 mm	15 mm	14 atm	DE-RQ3515KSM
3.5 mm	18 mm	14 atm	DE-RQ3518KSM
3.5 mm	21 mm	14 atm	DE-RQ3521KSM
3.5 mm	24 mm	14 atm	DE-RQ3524KSM
3.5 mm	28 mm	14 atm	DE-RQ3528KSM
3.5 mm	33 mm	14 atm	DE-RQ3533KSM
3.5 mm	38 mm	14 atm	DE-RQ3538KSM
4.0 mm	9 mm	14 atm	DE-RQ4009KSM
4.0 mm	12 mm	14 atm	DE-RQ4012KSM
4.0 mm	15 mm	14 atm	DE-RQ4015KSM
4.0 mm	18 mm	14 atm	DE-RQ4018KSM
4.0 mm	21 mm	14 atm	DE-RQ4021KSM
4.0 mm	24 mm	14 atm	DE-RQ4024KSM
4.0 mm	28 mm	14 atm	DE-RQ4028KSM
4.0 mm	33 mm	14 atm	DE-RQ4033KSM
4.0 mm	38 mm	14 atm	DE-RQ4038KSM

EC Design Examination Certificate

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith confirms that the design of the medical device (s)

Ultimaster™

Sirolimus eluting coronary stent system
Model numbers as per attachment 1 and 2

Ultimaster™ Tansei™

Sirolimus eluting coronary stent system
Model numbers as per attachment 3 and 4

of the manufacturer

TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

fulfills the below mentioned requirements of the **Council Directive 93/42/EEC**:

Annex II, Section 4

This certificate assumes that MEDCERT has to be informed about any changes of the approved design. Changes need further approval by MEDCERT.

This certificate is valid until: 29 January 2023

Report No.: 13090FS05F
Process No.: PP - 13090
Certificate No.: 13090GB411180413

Hamburg, 13 April 2018



MEDCERT Certification Body
(Dr. Andreas Schich)

MEDCERT Identification No.: 0482



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Attachment 1
EC Design Examination Certificate
PP - 13090

This attachment is valid only in connection with certificate No.: 13090GB411180413

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

Hamburg, 13 April 2018



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Attachment 2 EC Design Examination Certificate PP - 13090

This attachment is valid only in connection with certificate No.: 13090GB411180413

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

Hamburg, 13 April 2018


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Attachment 3 EC Design Examination Certificate PP - 13090

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

Hamburg, 13 April 2018

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Attachment 4 EC Design Examination Certificate PP - 13090

This attachment is valid only in connection with certificate No.: 13090GB411180413

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

Hamburg, 13 April 2018



MEDCERT Certification Body
(Dr. Andreas Schich)

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Certificate

The certification body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company

TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

with locations listed in the appendix

has introduced, applies and maintains a quality management system in the area of:

**Design and development, manufacture and final inspection of
Stent systems**

The conformity of this quality management system to the requirements of the below mentioned standard was verified by an audit:

EN ISO 13485:2016

This certification is subject to surveillance by MEDCERT.

Effective date: 2019-12-19
Expiry date: 2022-12-18

Report No.: 3179FS15F
Procedure No.: QS – 3479
Certificate No.: 3479GB445191217

Hamburg, 2019-12-17



MEDCERT Certification Body
(Dr. Andreas Schich)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT is a DAkkS accredited management systems
certification body

Appendix of certificate

Procedure No.: QS – 3479
Certificate No.: 3479GB445191217

List of locations included in the scope of certificate

Manufacturing site

Ashitaka Factory of Terumo Corporation
150, Maimaigi-cho, Fujinomiya City
Shizuoka Prefecture 418-0015
Japan

Designing site

Terumo Corporation, R&D Center
1500, Inokuchi, Nakai-machi, Ashigarakami-gun,
Kanagawa Prefecture 259-0151
Japan

– End of list –

This appendix is integral part of the above-referenced certificate.
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EC Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company:

TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

with locations listed in the appendix

has introduced, applies and maintains a quality assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex II without section 4

This certification is subject to surveillance by MEDCERT.

For the placing on the market of class III medical devices covered by this certificate, an additional EC design examination certificate according to Annex II, section 4 of Council Directive 93/42/EEC is required.

Effective date: 2019-12-17

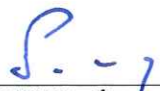
Expiry date: 2024-05-27

Report No.: 3479FS15F

Process No.: QS – 3479

Certificate No.: 3479GB410191217

Hamburg, 2019-12-17


MEDCERT Certification Body
(Dr. Andreas Schich)

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Form F10010005e EN / Rev. 11 / 2019.11.14



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Appendix of EC Certificate of Conformity

Process No.: QS – 3479

Certificate No.: 3479GB410191217

List of locations included in the scope of certificate**Manufacturing site**

Ashitaka Factory of Terumo Corporation
150, Maimaigi-cho, Fujinomiya City
Shizuoka Prefecture 418-0015
Japan

Designing site

Terumo Corporation, R&D Center
1500, Inokuchi, Nakai-machi, Ashigarakami-gun,
Kanagawa Prefecture 259-0151
Japan

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MEDCERT Identification Number: 0482



Appendix of EC Certificate of Conformity

Process No.: QS – 3479

Certificate No.: 3479GB410191217

List of products / product categories included in the scope of certificate

- **Stent systems**

– End of list –

This appendix is integral part of the above-referenced certificate.
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MEDCERT Identification Number: 0482

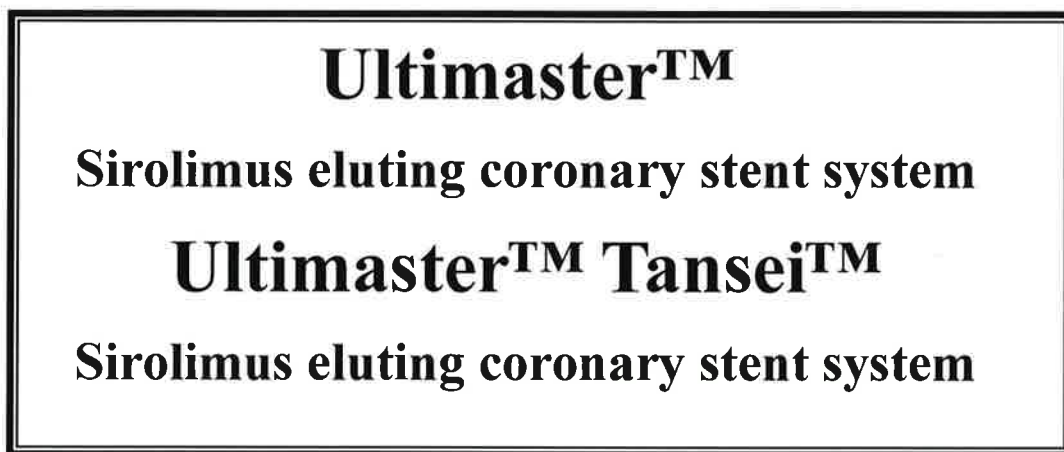


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DECLARATION OF CONFORMITY

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

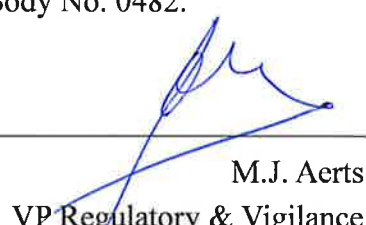
being the manufacturer of:



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: 13090GB411180413), 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, 18.12.2019
(place and date of issue)



M.J. Aerts
VP Regulatory & 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

