EC Design Examination Certificate

The Notified Body

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

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

> **Ultimaster™**
> **Sirolimus eluting coronary stent system**
>
> **Ultimaster™ Tansei™**
> **Sirolimus eluting coronary stent system**
>
> **with specifications listed in the appendix**

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.

For the placing on the market of medical devices covered by this certificate, a separate EC certificate of conformity according to Annex II without section 4 of Council Directive 93/42/EEC is required.

Effective date:	**2020-05-04**
Expiry date:	**2024-05-27**

Report No.:	13090FS07F
Process No.:	PP – 13090
Certificate No.:	13090GB411200504

Hamburg, 2020-05-04
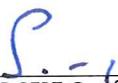
MEDCERT Certification Body
(Dr. Andreas Schich)

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To verify the validity of this certificate, contact info@medcert.de.

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Zentralstelle der Länder
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ZLG-BS-237.10.15

MEDCERT Identification Number: 0482

Appendix of EC Design Examination Certificate

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Specifiations

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

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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

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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

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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-RQ3009KSM	3.0	9
DE-RQ3012KSM	3.0	12
DE-RQ3015KSM	3.0	15
DE-RQ3018KSM	3.0	18
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DE-RQ3509KSM	3.5	9
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DE-RQ4024KSM	4.0	24
DE-RQ4028KSM	4.0	28
DE-RQ4033KSM	4.0	33
DE-RQ4038KSM	4.0	38

– End of list –

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