

# 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)

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

MEDCERT Identification Number: 0482

Form F10010009e EN / Rev. 7 / 2019.11.14



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[www.zlg.de](http://www.zlg.de)  
ZLG-BS-237.10.15

## Appendix of EC Design Examination Certificate

Process No.: PP – 13090  
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### Specifications

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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DE-RQ4028KSM	4.0	28
DE-RQ4033KSM	4.0	33
DE-RQ4038KSM	4.0	38

– End of list –

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