

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



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

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

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Attachment 2
EC Design Examination Certificate
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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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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

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Attachment 4 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-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

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