

EC Certificate



Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1191937-1

Manufacturer: Terumo Medical Corporation
950 Elkton Boulevard
Elkton MD 21921
USA

Products: Introducer Kits and Guiding Sheaths
Aspects of manufacture concerned with securing and maintaining sterility of
Vascular Compression Cuff

Replaces Approval, Registration No.: HD 60115912 0001

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 234172868-10
Effective date: 2021-05-18
Expiry date: 2024-05-26
Issue date: 2021-05-18



Songli
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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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TÜVRheinland®

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II (4)

Registration No.: ID 1191937-1

Manufacturer: Terumo Medical Corporation
950 Elkton Boulevard
Elkton MD 21921
USA

Products: Products Included:

Destination® Guiding Sheath
- carotid use (6 Fr, 7 Fr)
- renal use (5 Fr, 6 Fr, 7 Fr)
- peripheral use (5 Fr, 6 Fr, 7 Fr, 8 Fr)

The Notified Body hereby declares that an examination of the design dossier relating to the listed products has been performed according to Annex II, section 4 of the directive 93/42/EEC and that the design of the devices conforms to the requirements of the above-mentioned directive.

Report No.: 234171339-50

Effective date: 2021-05-06

Expiry date: 2024-05-26

Issue date: 2021-05-06



Dr. K. Kluge
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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

DECLARATION OF CONFORMITY

We, TERUMO MEDICAL CORPORATION
950 Elkton Blvd.
Elkton, Maryland USA 21921

being the manufacturer of:

Destination Guiding Sheath

Product: Carotid Guiding Sheath
Renal Guiding Sheath
Peripheral Guiding Sheath

Classification: Class III
Rule: 7, Invasive Device

Hereby declares the requirements of Annex II of the Directive 93/42/EEC have been met for the listed product. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive.

Under the supervision of TÜV Rheinland LGA Products GmbH (Registration No. HD and ID 1191937-1) as the Notified Body according to Directive 93/42/EEC concerning medical devices with the Identification Number 0197.

Authorized European Representative:
TERUMO EUROPE N.V.
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Leuven, Belgium

Elkton, Maryland USA / June 4, 2021
(Place of issue)


John Boselli
Sr. VP, Quality & Regulatory Affairs



1	2	3	4	5	
R	Radifocus Group				
	S	Guiding Sheath			
Carotid	C	90 cm Sheath			
		0	1	6 Fr, Straight Shape (ST), TBV Valve	
		0	2	7 Fr, Straight Shape (ST), TBV Valve	
		0	3	6 Fr, Multipurpose Shape (MP), TBV Valve	
		0	4	7 Fr, Multipurpose Shape (MP), TBV Valve	
		0	5	6 Fr, Straight Shape (ST), CCV Valve	
		0	6	7 Fr, Straight Shape (ST), CCV Valve	
		0	7	6 Fr, Multipurpose Shape (MP), CCV Valve	
		0	8	7 Fr, Multipurpose Shape (MP), CCV Valve	
Peripheral	P	65 cm Sheath			
		0	1	6 Fr, Straight Shape (ST), CCV Valve	
		0	2	7 Fr, Straight Shape (ST), CCV Valve	
		0	3	6 Fr, Straight Shape (ST), TBV Valve	
		0	4	7 Fr, Straight Shape (ST), TBV Valve	
Renal	R	45 cm Sheath			
		0	1	6 Fr, Straight Shape (ST), CCV Valve	
		0	2	6 Fr, Hockey-Stick Shape (HS), CCV Valve	
		0	3	6 Fr, Multipurpose Shape (MP), CCV Valve	
		1	3	6 Fr, Renal Double Curve Shape (RDC), CCV Valve	
		1	4	6 Fr, Left Internal Mammary Artery Shape (LIMA), CCV Valve	
		0	4	7 Fr, Straight Shape (ST), CCV Valve	
		0	5	7 Fr, Hockey-Stick Shape (HS), CCV Valve	
		0	6	7 Fr, Multipurpose Shape (MP), CCV Valve	
		1	5	7 Fr, Renal Double Curve Shape (RDC), CCV Valve	
		1	6	7 Fr, Left Internal Mammary Artery Shape (LIMA), CCV Valve	
		0	7	6 Fr, Straight Shape (ST), TBV Valve	
		0	8	6 Fr, Hockey-Stick Shape (HS), TBV Valve	
		0	9	6 Fr, Multipurpose Shape (MP), TBV Valve	
		1	7	6 Fr, Renal Double Curve Shape (RDC), TBV Valve	
		1	8	6 Fr, Left Internal Mammary Artery Shape (LIMA), TBV Valve	
		1	0	7 Fr, Straight Shape (ST), TBV Valve	
		1	1	7 Fr, Hockey-Stick Shape (HS), TBV Valve	
		1	2	7 Fr, Multipurpose Shape (MP), TBV Valve	
		1	9	7 Fr, Renal Double Curve Shape (RDC), TBV Valve	
		2	0	7 Fr, Left Internal Mammary Artery Shape (LIMA), TBV Valve	



1	2	3	4	5	6	7	8	
5	4	Destination						
		-						
5 Fr			5					
			Straight Shape (ST), CCV Valve, Extended Coating			0	1	
			Hockey Stick Shape, CCV Valve (HS)			0	2	
			Multipurpose Shape, CCV Valve (MP)			0	3	
			Renal Double Curve Shape, CCV Valve (RDC)			0	4	
6 Fr			6					
			Straight Shape (ST), CCV Valve, Extended Coating			0	1	
			Straight Shape (ST), TBV Valve, Extended Coating			0	6	
7 Fr			7					
			Straight Shape (ST), CCV Valve, Extended Coating			0	1	
			Straight Shape (ST), TBV Valve, Extended Coating			0	6	
8 Fr			8					
			Straight Shape (ST), CCV Valve, Extended Coating (45 & 90cm)			0	1	
			Straight Shape (ST), TBV Valve, Extended Coating (45 & 90cm)			0	6	
Length				4	5	45 cm Sheath		
				6	5	65 cm Sheath		
				9	0	90 cm Sheath		