Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care dețin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 4 din 13.10.2023

Solicitantul **FCPC „DataControl" S.R.L.**, cu sediul **mun. Chișinău, str. N. Testemițanu, 17/6**, tel./fax: 022 27 37 12, e-mail: contact@datacontrol.md, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Product: Angiographic Catheter

Model: RADIFOCUS Optitorque Angiographic Catheter

RH-4AL1000M	RH-6AL2000M	RH-5AR1000M	RH-5AR3000M	RH-4CL4000M
RH-5AL1000M	RH-4AL3000M	RH-6AR1000M	RH-5ARJP00M	RH-5CL4000M
RH-6AL1000M	RH-5AL3000M	RH-4AR2000M	RH-4CL3500M	RH-6CL4000M
RH-4AL2000M	RH-6AL3000M	RH-5AR2000M	RH-5CL3500M	RH-5CL4001M
RH-5AL2000M	RH-4AR1000M	RH-6AR2000M	RH-6CL3500M	RH-5CL4500M
RH-6CL4500M	RH-6CL6000M	RH-6JR4000M	RH-6CR4500M	RH-5MP2520M
RH-4CL5000M	RH-4CR3500M	RH-4CR4000M	RH-4CR5000M	RH-4MP3020M
RH-5CL5000M	RH-5CR3500M	RH-5CR4000M	RH-5CR5000M	RH-4SP006GM
RH-6CL5000M	RH-6CR3500M	RH-6CR4000M	RH-6CR5000M	RH-5SP006GM
RH-5CL6000M	RH-5CR3521M	RH-6CR4100M	RH-4MP2520M	RH-4SP0068M
RH-4SP0069M	RH-5AP4561M	RH-4APR241M	RH-BA35110M	
RH-4SP0061M	RH-6AP4561M	RH-BA14110M	RH-BH14110M	
RH-5SP0061M	RH-4AP5561M	RHBA24110M	RH-BH15110M	
RH-6SP0061M	RH-5AP5561M	RH-BA25110M	RH-BHB5110M	
RH-4AP4561M	RH-6AP5561M	RH-BA34110M		

Se anexează următoarele acte:

1. Declarație de Conformitate CE
2. Certificatul de Conformitate CE
3. Actul prin care producătorul își desemnează reprezentantul
4. Declarație pe propria răspundere.

Data **13.10.2023** Semnătura _____

Tabelul de receptionare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Digitally signed by Grabazel Alexandru
Date: 2023.10.13 15:31:59 EEST
Reason: MoldSign Signature
Location: Moldova

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Către
Agenţia Medicamentului
şi Dispozitivelor Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitantul **F.C.P.C. ”DataControl” S.R.L.**, cu sediul în **mun. Chișinău, str. N. Testemițanu 17/6**, tel./fax: **022 27 37 12**, e-mail: contact@datacontrol.md,

declar pe proprie răspundere, cunoscînd prevederile art. **352[1]** , Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

Product: Angiographic Catheter

Model: RADIFOCUS Optitorque Angiographic Catheter

RH-4AL1000M	RH-6AL2000M	RH-5AR1000M	RH-5AR3000M	RH-4CL4000M
RH-5AL1000M	RH-4AL3000M	RH-6AR1000M	RH-5ARJP00M	RH-5CL4000M
RH-6AL1000M	RH-5AL3000M	RH-4AR2000M	RH-4CL3500M	RH-6CL4000M
RH-4AL2000M	RH-6AL3000M	RH-5AR2000M	RH-5CL3500M	RH-5CL4001M
RH-5AL2000M	RH-4AR1000M	RH-6AR2000M	RH-6CL3500M	RH-5CL4500M
RH-6CL4500M	RH-6CL6000M	RH-6JR4000M	RH-6CR4500M	RH-5MP2520M
RH-4CL5000M	RH-4CR3500M	RH-4CR4000M	RH-4CR5000M	RH-4MP3020M
RH-5CL5000M	RH-5CR3500M	RH-5CR4000M	RH-5CR5000M	RH-4SP006GM
RH-6CL5000M	RH-6CR3500M	RH-6CR4000M	RH-6CR5000M	RH-5SP006GM
RH-5CL6000M	RH-5CR3521M	RH-6CR4100M	RH-4MP2520M	RH-4SP0068M
RH-4SP0069M	RH-5AP4561M	RH-4APR241M	RH-BA35110M	
RH-4SP0061M	RH-6AP4561M	RH-BA14110M	RH-BH14110M	
RH-5SP0061M	RH-4AP5561M	RHBA24110M	RH-BH15110M	
RH-6SP0061M	RH-5AP5561M	RH-BA25110M	RH-BHB5110M	
RH-4AP4561M	RH-6AP5561M	RH-BA34110M		

Sunt autentice și corespund realității

Alexandru Grabazei, director Semnătura _____

Data: **13.10.2023**

Terumo Europe NV
Emerging Market Division

Researchpark Haasrode 1520
Interleuvenlaan 40
3001 Leuven, Belgium
Tel.: +32 16 38 13 08
Fax: +32 16 38 16 01

www.terumo-europe.com

To: Whom It May Concern

Ref: 2023/007/IS/MI

Leuven, January 18, 2023

Letter of Authorization

We, begin company-manufacturer **Terumo Europe N.V. (Belgium);**
and being the European Authorized representative of company-manufacturer **Terumo Corporation**, **Terumo Medical Corporation**, **Terumo Clinical Supply and Terumo Medical Products (Hangzhou)**;
and being the appointed distributor for products from the company-manufacturer **PendraCare, MicroVention Europe, MicroVention Inc and Kaneka Corporation;**

hereby appoint following company (hereinafter - "Company"):

FCPC "DataControl" SRL
20 Melestiu Street, MD-2001,
Chisinau, Republic of Moldova,

to be our official representative at the responsible authorities of the Republic of Moldova for registration, renewal, variation of registration etc. of following medical products and devices manufactured and/or distributed by us:

Accuforce PTCA dilatation catheter (RX)
Angio-Seal VIP Vascular Closure Device
Azur Detachment Controller
Azur Peripheral Coil System
Climber Guiding Catheter
Crosperio RX PTA Balloon Dilatation Catheter
Crosstella OTW PTA Balloon Dilatation Catheter
Destination Guiding Sheath *(Terumo Corporation and Terumo Medical Corporation)*
Eliminate Aspiration catheter
FemoSeal Vascular Closure System
Finecross MG Coronary Micro-Guide catheter
Glidesheath Slender Hydrophilic Coated Introducer Sheath
Heartrail II Guiding Catheter
HydroPearl Compressible Microspheres for Embolisation
LifePearl Drug-elutable microspheres for embolisation
Metacross® OTW PTA Balloon Dilatation Catheter
Metacross® RX PTA Balloon Dilatation Catheter
Navicross Support Catheter
Occlusafe Temporary Occlusion Balloon Catheter
Outlook Angiographic Catheter
Progreat Micro Catheter System *(Terumo Corporation and Terumo Clinical Supply)*
Radifocus Glidecath Angiographic Catheter *(Terumo Corporation and Terumo Europe)*

Radifocus Guide Wire GT with Gold Coil
Radifocus Guide Wire M *(Terumo Corporation and Terumo Europe)*
Radifocus Guide Wire M Non-Vascular
RADIFOCUS® Glidewire Advantage™
RADIFOCUS® Glidewire Advantage™ Track
Radifocus Obturator
Radifocus Torque Device *(Terumo Corporation and Terumo Medical Products (Hangzhou))*
Radifocus Vessel Dilator
Radifocus OPTITORQUE Angiographic Catheter *(Terumo Corporation and Terumo Europe)*
Radifocus Introducer II (Transradial Kit)
Radifocus Introducer II
Roadsaver Carotid Artery Stent
Runthrough® NS Extension Wire PTCA Guide Wire
Runthrough® NS PTCA Guide Wire
Ryujin Plus PTCA dilatation catheter (RX)
Senri® PTA Balloon Dilatation catheter
Tercross® PTA Dilatation Catheter (OTW)
Ryurei PTCA Dilatation Catheter
TR Band Radial Artery Haemostasis Band
Ultimaster Sirolimus eluting coronary stent system
Ultimaster Tansei Sirolimus eluting coronary stent system
Ultimaster Nagomi Sirolimus eluting coronary stent system

Hereby the Company is authorized to ensure that state registration (re-registration) of the abovementioned products is obtained and maintained in accordance with the legislation of Republic of Moldova.

For this purpose, the company can perform all acts, including but not limited: to submit, confirm, receive all necessary documents, including registration certificates, to reply to inquiries, questions or other communications from authorized institutions, after consultation with Regulatory department of Terumo Europe N.V, to conduct any field actions which may be necessary, in accordance with legislation of Republic of Moldova.

Registration certificates must be issued in the name of Terumo Europe N.V.

This authorization letter is valid for a period of 12 /twelve/ months from the date of issue, unless revoked earlier by Terumo Europe N.V.

For and behalf of Terumo Europe N.V.:

TERUMO
TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 LEUVEN, BELG.

Valérie Boydens

Director Regulatory Affairs
Terumo Europe NV

TÜVRheinland®

EC Design-Examination Certificate

Directive 93/42/EEC Annex II, Section 4

Medical Devices

Registration No.: ID 60149181 0001

Report No.: 21257349 003

Manufacturer:

TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Product Identification:

Catheter, Angiography
RADIFOCUS OPTITORQUE

(see attachment for products included)
Replaces certificate, Registration No.: ID 60114894 0001

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 abovementioned directive.

Expiry Date: 2024-05-26

Effective Date: 2020-05-07

Date: 2020-05-07

Notified Body

TÜVRheinland LGA Products GmbH

Dipl.-Ing. S. Pane

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to certificate
Registration No.: ID 60149181 0001
Report No.: 21257349 003

Manufacturer: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Radifocus Optitorque

Product code system

(1) Thoracic use

R	H	-	□	□	□	□	□	□	□	□
1	2	3	4	5	6	7	8	9	10	11

Position	Indication & Meaning
1-2	Product name RH: Radifocus® Optitorque™
3	Manufacturing site -: TERUMO Europe N.V.
4	Outer diameter of catheter Indication: 4, 5 6 Size (Fr.): 4 (1.40 mm); 5 (1.70 mm); 6 (2.00 mm)
5-8	Tip shape: 4 alphanumerical digits
9	Number of side holes Indication: 0 ~ 9 Number of side holes: 0 - 9
10	Catheter Length
	Indication : 6 G 7 8 9 0 1 Length (cm): 60 65 70 80 90 100 110
11	Language used for the indications M: Multi-language

Date, 2020-05-07

TÜV Rheinland LGA Products GmbH
Notified Body
TÜVRheinland
Dipl.-Ing. S. Patre

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to certificate
Registration No.: **ID 60149181 0001**
Report No.: **21257349 003**

Manufacturer: **TERUMO EUROPE N.V.**
Interleuvenlaan 40
3001 Leuven
Belgium

Radifocus Optitorque

(2) Visceral & Cerebral use

R	H	-	□	□	□	□	□	□	□	□
1	2	3	4	5	6	7	8	9	10	11

Position	Indication & Meaning
1-2	Product name RH: Radifocus® Optitorque™
3	Production site -: TERUMO Europe N.V.
4	Indication of catheter use A : visceral use B : cerebral use
5-6	Tip shape, including number of side holes: 2 Alphanumerical digits
7	Outer diameter of catheter Indication: 4, 5 Size (Fr.): 4 (1.40 mm); 5 (1.70 mm)
8	Availability of stopcock 1 : Without stopcock
9-10	Catheter Length
	Indication: 02 0G 07 08 09 10 11 Length (cm): 20 65 70 80 90 100 110
11	Language used for the indications M: Multi-language

TÜV Rheinland LGA Products GmbH
Notified Body
TÜVRheinland

Date, 2020-05-07

Dipl.-Ing. S. Pane

TÜVRheinland®

EC Design-Examination Certificate

Directive 93/42/EEC Annex II, Section 4

Medical Devices

Registration No.: ID 60149172 0001

Report No.: 21257349 004

Manufacturer:

Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo
151-0072 Japan

Product Identification:

Catheter, Angiography
RADIFOCUS OPTITORQUE

(see attachment for products included)

Replaces Certificate, Registration No.: ID 60114893 0001

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 abovementioned directive.

Expiry Date: 2024-05-26

Effective Date: 2020-05-07

Date: 2020-05-07

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierstelle TÜVRheinland®

Dipl.-Ing. S. Pane

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to certificate
Registration No.: ID 60149172 0001
Report No.: 21257349 004

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Radifocus Optitorque

Product code system

Thoracic use

R	H	+/*	□	□	□	□	□	□	□	□	□
1	2	3	4	5	6	7	8	9	10	11	12

Position	Characters & Meaning
1-2	Product type RH: Radifocus® Optitorque™
3	Destination * : for worldwide excluding Japan (Manufactured by Terumo Co. Ashitaka factory) +/*: for worldwide excluding Japan and U.S.A (Manufactured by Terumo Vietnam Co.,Ltd)
4	Outer diameter of catheter Character: 4 5 6 Diameter: 4 Fr.(1.40 mm) 5 Fr.(1.70 mm) 6 Fr.(2.00 mm)
5-8	Tip shape: 4 alphanumerical digits
9	Number of side holes Character: 0 1 2 4 6 8 Number: 0 1 2 4 6 8
10	Catheter Length Character: 4 E 5 F 6 G 7 H 8 I 9 Length(cm): 40 45 50 55 60 65 70 75 80 85 90 Character : J 0 K 1 L 2 N Length(cm): 95 100 105 110 115 120 125 * The maximum catheter length for the following tip shapes is 100 cm: 3D-Right Modified and 3D RC
11	Braid cut length: Q: 60 mm (For products whose braid cut length is not 60mm, the product code consists of 11 characters and the 11th character denotes the language for labelling)
12	Languages used for the indications M: Multi-language

Notified Body

Date 2020-05-07

Dipl.-Ing. S. Pane

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to certificate
Registration No.: **ID 60149172 0001**
Report No.: **21257349 004**

Manufacturer: **Terumo Corporation**
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Radifocus Optitorque

Visceral and Celebral use

R	H	+/*	□	□	□	□	□	□	□	□
1	2	3	4	5	6	7	8	9	10	11

Position	Characters & Meaning
1-2	Product type RH: Radifocus® Optitorque™
3	Destination * : for worldwide excluding Japan (Manufactured by Terumo Co. Ashitaka factory) +/*: for worldwide excluding Japan and U.S.A (Manufactured by Terumo Vietnam Co.,Ltd)
4	Indication of catheter use: A : visceral use B : cerebral use
5-6	Tip shape: 2 alphanumerical digits
7	Outer diameter of catheter Character: 4 5 Diameter: 4 Fr.(1.40 mm) 5 Fr.(1.70 mm)
8	Availability of stopcock 1 : Without stopcock
9-10	Catheter Length
	Character: 02 03 04 05 06 0G 07 0H 08 0I 09 Length(cm): 20 30 40 50 60 65 70 75 80 85 90
	Character: 0J 10 1A 11 1B 12 1C Length(cm): 95 100 105 110 115 120 125
11	Language used for the indications M: Multi-language

Notified Body

Dipl.-Ing. S. Pane

Date 2020-05-07

TÜVRheinland®

EC Design-Examination Certificate

Directive 93/42/EEC Annex II, Section 4

Medical Devices

Registration No.: ID 60149172 0001

Report No.: 21257349 004

Manufacturer:

Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo
151-0072 Japan

Product Identification:

Catheter, Angiography
RADIFOCUS OPTITORQUE

(see attachment for products included)

Replaces Certificate, Registration No.: ID 60114893 0001

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 abovementioned directive.

Expiry Date: 2024-05-26

Effective Date: 2020-05-07

Date: 2020-05-07

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierstelle TÜVRheinland®

Dipl.-Ing. S. Pane

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to certificate
Registration No.: ID 60149172 0001
Report No.: 21257349 004

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Radifocus Optitorque

Product code system

Thoracic use

R	H	+/*	□	□	□	□	□	□	□	□	□
1	2	3	4	5	6	7	8	9	10	11	12

Position	Characters & Meaning
1-2	Product type RH: Radifocus® Optitorque™
3	Destination * : for worldwide excluding Japan (Manufactured by Terumo Co. Ashitaka factory) +/*: for worldwide excluding Japan and U.S.A (Manufactured by Terumo Vietnam Co.,Ltd)
4	Outer diameter of catheter Character: 4 5 6 Diameter: 4 Fr.(1.40 mm) 5 Fr.(1.70 mm) 6 Fr.(2.00 mm)
5-8	Tip shape: 4 alphanumerical digits
9	Number of side holes Character: 0 1 2 4 6 8 Number: 0 1 2 4 6 8
10	Catheter Length Character: 4 E 5 F 6 G 7 H 8 I 9 Length(cm): 40 45 50 55 60 65 70 75 80 85 90 Character : J 0 K 1 L 2 N Length(cm): 95 100 105 110 115 120 125 * The maximum catheter length for the following tip shapes is 100 cm: 3D-Right Modified and 3D RC
11	Braid cut length: Q: 60 mm (For products whose braid cut length is not 60mm, the product code consists of 11 characters and the 11th character denotes the language for labelling)
12	Languages used for the indications M: Multi-language

Notified Body

Date 2020-05-07

Dipl.-Ing. S. Pane

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to certificate
Registration No.: **ID 60149172 0001**
Report No.: **21257349 004**

Manufacturer: **Terumo Corporation**
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Radifocus Optitorque

Visceral and Celebral use

R	H	+/*	□	□	□	□	□	□	□	□
1	2	3	4	5	6	7	8	9	10	11

Position	Characters & Meaning
1-2	Product type RH: Radifocus® Optitorque™
3	Destination * : for worldwide excluding Japan (Manufactured by Terumo Co. Ashitaka factory) +/*: for worldwide excluding Japan and U.S.A (Manufactured by Terumo Vietnam Co.,Ltd)
4	Indication of catheter use: A : visceral use B : cerebral use
5-6	Tip shape: 2 alphanumerical digits
7	Outer diameter of catheter Character: 4 5 Diameter: 4 Fr.(1.40 mm) 5 Fr.(1.70 mm)
8	Availability of stopcock 1 : Without stopcock
9-10	Catheter Length
	Character: 02 03 04 05 06 0G 07 0H 08 0I 09 Length(cm): 20 30 40 50 60 65 70 75 80 85 90
	Character: 0J 10 1A 11 1B 12 1C Length(cm): 95 100 105 110 115 120 125
11	Language used for the indications M: Multi-language

Notified Body

Dipl.-Ing. S. Pane

Date 2020-05-07

EC Certificate

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

Registration No.: HD 60145252 0001

Report No.: 12031336 018

Manufacturer:
Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo
151-0072 Japan

Products: see attachement for products included

Replaces Approval, Registration No.: HD 60121893 0001

Expiry Date: 2024-05-26

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.

Effective Date: 2019-12-23

Date: 2019-12-23

Notified Body

M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/2, Rev.1

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60145252 0001
Report No.: 12031336 023

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-ku, Tokyo
151-0072 Japan

Products included:

- Blood Bags
- Blood Donor Set with/without Blood Transfusion Filter
- Blood Transfusion Filter
- Intravenous Catheter
- Intravenous Administration Set
- Hypodermic Syringe
- Winged Needle
- Dental Needle
- Other Medical Needle
- Blood Administration Set
- Lancet

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Date: 2020-10-23

M.Sc. M. Aihara

TÜVRheinland®

Doc. 2/2, Rev.1

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60145252 0001
Report No.: 12031336 023

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-ku, Tokyo
151-0072 Japan

Products included:
- Extra-corporeal Membrane Oxygenator
- Cardiopulmonary Bypass Arterial Line Blood Filter
- Heart-Lung Bypass Defoamer
- Cardiotomy Reservoir
- Cardiopulmonary Bypass Blood Reservoir
- Haemoconcentration Filter
- Centrifugal Pump
- Angiographic Catheter
- Balloon Dilatation Catheter
- Catheter Guide Wire
- Guiding Catheter
- Catheter Introducer
- Stents
- Extension Tube
- Temperature Control Unit for Heart-Lung Bypass System Module
- Infusion Pump
- Syringe Infusion Pump
- Clinical Electronic Thermometer
- Portable insulin infusion pump
- Portable insulin infusion administration set

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2020-10-23

M.Sc. M. Aihara

EC Certificate

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

Registration No.: HD 60145252 0001

Report No.: 12031336 018

Manufacturer:
Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo
151-0072 Japan

Products: see attachement for products included

Replaces Approval, Registration No.: HD 60121893 0001

Expiry Date: 2024-05-26

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.

Effective Date: 2019-12-23

Date: 2019-12-23

Notified Body

M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/2, Rev.1

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60145252 0001
Report No.: 12031336 023

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-ku, Tokyo
151-0072 Japan

Products included:

- Blood Bags
- Blood Donor Set with/without Blood Transfusion Filter
- Blood Transfusion Filter
- Intravenous Catheter
- Intravenous Administration Set
- Hypodermic Syringe
- Winged Needle
- Dental Needle
- Other Medical Needle
- Blood Administration Set
- Lancet

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Date: 2020-10-23

M.Sc. M. Aihara

TÜVRheinland®

Doc. 2/2, Rev.1

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60145252 0001
Report No.: 12031336 023

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-ku, Tokyo
151-0072 Japan

Products included:
- Extra-corporeal Membrane Oxygenator
- Cardiopulmonary Bypass Arterial Line Blood Filter
- Heart-Lung Bypass Defoamer
- Cardiotomy Reservoir
- Cardiopulmonary Bypass Blood Reservoir
- Haemoconcentration Filter
- Centrifugal Pump
- Angiographic Catheter
- Balloon Dilatation Catheter
- Catheter Guide Wire
- Guiding Catheter
- Catheter Introducer
- Stents
- Extension Tube
- Temperature Control Unit for Heart-Lung Bypass System Module
- Infusion Pump
- Syringe Infusion Pump
- Clinical Electronic Thermometer
- Portable insulin infusion pump
- Portable insulin infusion administration set

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2020-10-23

M.Sc. M. Aihara

EC Certificate

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

Registration No.: HD 60134707 0001

Report No.: 21240046 017

Manufacturer:
TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Products: (see attachment for products and additional sites included)

Replaces Certificate, Registration No.: HD 60106290 0001

Expiry Date: 2024-05-26

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.

Notified Body

Effective Date: 2020-04-21

Date: 2020-04-21

Dipl.-Ing. (FH) D. Wiedemuth

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60134707 0001
Report No.: 21240046 017

Manufacturer: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Products included:

- Syringes
- Needles
- Administration sets
- Extra corporeal circuits for open heart surgery
- Non-vascular guide wires
- Introducer for vascular access
- Angiographic Catheters
- Guidewire for Angiography

For the following devices the scope covers only the aspects of the manufacture concerned with the securing and maintaining sterile conditions:
- Ancillary devices for extracorporeal circuits for open heart surgery
- Mixing needles

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Prüfstelle

Date: 2020-04-21

Dipl.-Ing. (FH) D. Wiedemuth

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60134707 0001
Report No.: 21240046 017

Manufacturer: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

additional sites included:

Terumo Europe N.V.
European Distribution Center
Brikkenovenstraat 48
3600 Genk, Belgium

Terumo Europe UK
3 Unity Grove, Knowsley Business Park South
Knowsley, Merseyside L34 9GT, United Kingdom

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Prüfzertifizierungsstelle

Date: 2020-04-21

Dipl.-Ing. (FH) D. Wiedemuth

DECLARATION OF CONFORMITY

We, TERUMO CORPORATION
44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan

being the manufacturer of:

RADIFOCUS Optitorque

Angiographic Catheter

Product : Angiographic Catheter

declare that the above products of **Class III** are in conformity with the provisions of the EC Council Directive 93/42/EEC of 14 June 1993, as amended, concerning medical devices, and have been subject to the conformity assessment procedure laid down in Article 11, 1(a) of the Directive, relating to the "Full quality assurance" set out in Annex II, and by certification of Annex II, excluding Section 4 (Registration No.: HD 60145252 0001), and Annex II, Section 4 (Registration No.: ID 60149172 0001) under the supervision of TÜV Rheinland LGA Products GmbH, Tillystraße 2, 90431 Nürnberg Germany, as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0197.

Authorized European Representative:
TERUMO EUROPE N.V.
Interleuvenlaan 40, 3001 Leuven, Belgium

Object of the declaration: see appendix A

Tokyo, June 09, 2020
(place and date of issue)

Toshio Nakashima
General Manager
Quality Assurance Department
TERUMO CORPORATION

Appendix A - List of Code Number Structure

R	H	□	□	□	□	□	□	□	□	□	□
1	2	3	4	5	6	7	8	9	10	11	12

1) Thoracic use

Character number	Meaning of indication		
1-2	Product type RH : Radifocus® Optitorque™		
3	Destination * : for export (Manufactured by Terumo Co. Ashitaka factory) + / * : for export excluding Japan (Manufactured by Terumo Vietnam Co., Ltd)		
4	Outer diameter of catheter (indication on labelling) 4 : 4 Fr. (1.40 mm), 5 : 5 Fr. (1.70 mm), 6 : 6 Fr. (2.00 mm)		
5-8	Tip shape Indication of tip configuration: these four digits are specific for each tip shape.		
	Four digits	Tip shape	Tip curve length
	AL10	AMPLATZ LEFT	Small
	AL20	AMPLATZ LEFT	Middle
	AL30	AMPLATZ LEFT	Large
	AP45	Angled Pigtail 145°	5.5 cm
	AP55	Angled Pigtail 155°	5.5 cm
	AP65	Angled Pigtail 165°	5.5 cm
	APR2	Angled Pigtail Round Type 155°	2.0 cm
	AR10	AMPLATZ RIGHT	Small
	AR20	AMPLATZ RIGHT	Middle
	AR30	AMPLATZ RIGHT	Large
	ARJP	AMPLATZ RIGHT Type JP	Small
	ARR5	AMPLATZ MODIFIED Type NTR r5	—
	ARRC	AMPLATZ MODIFIED Type NTR	—
	BL35	Jacky Radial	3.5 cm
	BL40	Sarah Radial	4.0 cm
	BLK4	Radial BLK	4.0 cm
	BPIG	LIMA	—
	BPIM	Internal Mammary (Round tip)	—
	BPIN	Internal Mammary	—
	BPIR	Internal Mammary	—
	BPJL	Bypass Judkins Left	—
	BPJP	Internal Mammary Type JP	—
	BPJR	Bypass Judkins Right	—
	BPRB	Radial Internal Mammary Type RB	—
	BU35	BACKUP LEFT	3.5 cm
	CAS1	CASTILLO 1	Small
	CAS2	CASTILLO 2	Middle

5-8	CL35	JUDKINS LEFT	3.5 cm
	CL40	JUDKINS LEFT	4.0 cm
	CL45	JUDKINS LEFT	4.5 cm
	CL50	JUDKINS LEFT	5.0 cm
	CL60	JUDKINS LEFT	6.0 cm
	CR35	JUDKINS RIGHT	3.5 cm
	CR40	JUDKINS RIGHT	4.0 cm
	CR45	JUDKINS RIGHT	4.5 cm
	CR50	JUDKINS RIGHT	5.0 cm
	CR60	JUDKINS RIGHT	6.0 cm
	FJ10	Amplatz Right Modified	—
	JL35	JUDKINS LEFT	3.5 cm
	JL40	JUDKINS LEFT	4.0 cm
	JL50	JUDKINS LEFT	5.0 cm
	JL60	JUDKINS LEFT	6.0 cm
	JR35	JUDKINS RIGHT	3.5 cm
	JR40	JUDKINS RIGHT	4.0 cm
	JR50	JUDKINS RIGHT	5.0 cm
	JR60	JUDKINS RIGHT	6.0 cm
	MP25	Multipurpose	2.5 cm
	MP30	Multipurpose	3.0 cm
	MP35	Multipurpose	3.5 cm
	MP40	Multipurpose	4.0 cm
	PL15	Baby Judkins Left	1.5 cm
	PL20	Baby Judkins Left	2.0 cm
	PL25	Baby Judkins Left	2.5 cm
	PL30	Baby Judkins Left	3.0 cm
	PR15	Baby Judkins Right	1.5 cm
	PR20	Baby Judkins Right	2.0 cm
	PR25	Baby Judkins Right	2.5 cm
	PR30	Baby Judkins Right	3.0 cm
	RD30	3D-Right Modified	3.0 cm
	RD40	3D RC	4.0 cm
	SAL1	AL 1	small
	SAL2	AL 2	middle
	SL35	JUDKINS LEFT	3.5 cm
	SL40	JUDKINS LEFT	4.0 cm
	SL50	JL 5.0	5.0 cm

5-8	SP00	Straight Pigtail	—
	SP02	Straight Pigtail	Small Loop
	ST01	Straight (without soft tip)	—
	TIG1	Radial TIG	4.0 cm
	TIG2	Radial TIG 4.5	4.5 cm
	TR35	Radial TIG II 3.5	3.5 cm
	TR40	Radial TIG II 4.0	4.0 cm
	TR45	Radial TIG II 4.5	4.5 cm
	TR50	Radial TIG II 5.0	5.0 cm
9	Number of holes : Character : 0 1 2 4 6 8 Number : 0 1 2 4 6 8		
10	**Catheter length** Character 4 E 5 F 6 G 7 H 8 I 9 Length (cm) 40 45 50 55 60 65 70 75 80 85 90 Character J 0 K 1 L 2 N Length (cm) 95 100 105 110 115 120 125 * The maximum catheter length for the following tip shapes is 100 cm: 3D-Right Modified and 3D RC		
11	Braid cut length Q : 60 mm (For products whose braid cut length is not 60mm, the product code consists of 11 characters and the 11th character denotes the language for labeling.)		
12	**Languages used for the indications** M: Multi-language		

2) Visceral and cerebral use

Character number	Meaning of indication			
1-2	Product type RH : Radifocus® Optitorque™			
3	Destination * : for export (Manufactured by Terumo Co. Ashitaka factory) + / * : for export excluding Japan (Manufactured by Terumo Vietnam Co., Ltd)			
4	Indication of catheter use A : Visceral use, B : Cerebral use			
5-6	Tip shape Indication of tip configuration: these two digits together with digit 4 makes an unique code specific for each tip shape and number of side holes			
	Two digits	Tip shape	Tip curve length	Side holes
	Visceral use			
	AF	AAF	—	6
	B4	Cobra1 (C1)	Small	None
	B5	Cobra2 (C2)	Middle	None

5-6	B6	Cobra3 (C3)	Large	None
	BI	Cobra1 (C1)	Small	1
	C3	SHEPHERD HOOK	0.8cm	None
	C4	SHEPHERD HOOK	1.0cm	None
	D1	J Curve	7.0cm	None
	D4	J Curve	Large	None
	D5	J Curve	Middle	None
	D6	J Curve	Small	None
	E4	SIDEWINDER	1	None
	E5	SIDEWINDER	2	None
	E6	SIDEWINDER	3	None
	EC	MESENT	—	1
	ED	SIDEWINDER Type: S-J	1	None
	F1	Mikaelsson (1)	—	None
	G1	RLG	—	None
	G3	RH	—	None
	G4	RS	—	None
	G9	YASHIRO TYPE	—	None
	GF	RH Modified	—	None
	M7	Straight	—	None
	R9	RH CK TYPE	—	None
	UB	UFE Type 1	19 cm	None
	ZX	Straight	—	8
	Cerebral use			
	A1	Simmons/Sidewinder 1	Sim1	None
	A2	Simmons/Sidewinder 2	Sim2	None
	A3	Simmons/Sidewinder 3	Sim3	None
	B1	Hinck Headhunter 1	H1	None
	B2	HEADHUNTER	3	None
	B3	HEADHUNTER	4	None
	C1	NEWTON TECHNIQUE	1	None
	C2	NEWTON TECHNIQUE	2	None
	C3	NEWTON TECHNIQUE	3	None
	E1	Bentson-Hanafee-Wilson 1	JB1	None
	E2	Bentson-Hanafee-Wilson 2	JB2	None
	G1	Mani	—	None
	H1	Vertebral	—	None
	H8	Vertebral	—	2
	H9	Vertebral Bolia Mini Cath	—	None
	K9	Sliding Curve	—	None
	L1	BERENSTEIN	BL1	None
	R5	Hinck Headhunter 1	Short tip	None

5-6	R7	MEDULLAR II	Middle	None
	R8	MEDULLAR I	Small	None
	R9	MEDULLAR III	Large	None

7	Outer diameter of catheter (indication on labelling) 4 : 4 Fr. (1.40 mm), 5 : 5 Fr. (1.70 mm)
8	**Availability of stopcock** 1 : without stopcock
9-10	**Catheter length** Character 02 03 04 05 06 0G 07 0H 08 0I 09 Length (cm) 20 30 40 50 60 65 70 75 80 85 90 Character 0J 10 1A 11 1B 12 1C Length (cm) 95 100 105 110 115 120 125
11	**Languages used for the indications** M: Multi-language

DECLARATION OF CONFORMITY

We, TERUMO CORPORATION
44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan

being the manufacturer of:

RADIFOCUS Optitorque

Angiographic Catheter

Product : Angiographic Catheter

declare that the above products of **Class III** are in conformity with the provisions of the EC Council Directive 93/42/EEC of 14 June 1993, as amended, concerning medical devices, and have been subject to the conformity assessment procedure laid down in Article 11, 1(a) of the Directive, relating to the "Full quality assurance" set out in Annex II, and by certification of Annex II, excluding Section 4 (Registration No.: HD 60145252 0001), and Annex II, Section 4 (Registration No.: ID 60149172 0001) under the supervision of TÜV Rheinland LGA Products GmbH, Tillystraße 2, 90431 Nürnberg Germany, as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0197.

Authorized European Representative:
TERUMO EUROPE N.V.
Interleuvenlaan 40, 3001 Leuven, Belgium

Object of the declaration: see appendix A

Tokyo, June 09, 2020
(place and date of issue)

Toshio Nakashima
General Manager
Quality Assurance Department
TERUMO CORPORATION

Appendix A - List of Code Number Structure

R	H	□	□	□	□	□	□	□	□	□	□
1	2	3	4	5	6	7	8	9	10	11	12

1) Thoracic use

Character number	Meaning of indication		
1-2	Product type RH : Radifocus® Optitorque™		
3	Destination * : for export (Manufactured by Terumo Co. Ashitaka factory) + / * : for export excluding Japan (Manufactured by Terumo Vietnam Co., Ltd)		
4	Outer diameter of catheter (indication on labelling) 4 : 4 Fr. (1.40 mm), 5 : 5 Fr. (1.70 mm), 6 : 6 Fr. (2.00 mm)		
5-8	Tip shape Indication of tip configuration: these four digits are specific for each tip shape.		
	Four digits	Tip shape	Tip curve length
	AL10	AMPLATZ LEFT	Small
	AL20	AMPLATZ LEFT	Middle
	AL30	AMPLATZ LEFT	Large
	AP45	Angled Pigtail 145°	5.5 cm
	AP55	Angled Pigtail 155°	5.5 cm
	AP65	Angled Pigtail 165°	5.5 cm
	APR2	Angled Pigtail Round Type 155°	2.0 cm
	AR10	AMPLATZ RIGHT	Small
	AR20	AMPLATZ RIGHT	Middle
	AR30	AMPLATZ RIGHT	Large
	ARJP	AMPLATZ RIGHT Type JP	Small
	ARR5	AMPLATZ MODIFIED Type NTR r5	—
	ARRC	AMPLATZ MODIFIED Type NTR	—
	BL35	Jacky Radial	3.5 cm
	BL40	Sarah Radial	4.0 cm
	BLK4	Radial BLK	4.0 cm
	BPIG	LIMA	—
	BPIM	Internal Mammary (Round tip)	—
	BPIN	Internal Mammary	—
	BPIR	Internal Mammary	—
	BPJL	Bypass Judkins Left	—
	BPJP	Internal Mammary Type JP	—
	BPJR	Bypass Judkins Right	—
	BPRB	Radial Internal Mammary Type RB	—
	BU35	BACKUP LEFT	3.5 cm
	CAS1	CASTILLO 1	Small
	CAS2	CASTILLO 2	Middle

5-8	CL35	JUDKINS LEFT	3.5 cm
	CL40	JUDKINS LEFT	4.0 cm
	CL45	JUDKINS LEFT	4.5 cm
	CL50	JUDKINS LEFT	5.0 cm
	CL60	JUDKINS LEFT	6.0 cm
	CR35	JUDKINS RIGHT	3.5 cm
	CR40	JUDKINS RIGHT	4.0 cm
	CR45	JUDKINS RIGHT	4.5 cm
	CR50	JUDKINS RIGHT	5.0 cm
	CR60	JUDKINS RIGHT	6.0 cm
	FJ10	Amplatz Right Modified	—
	JL35	JUDKINS LEFT	3.5 cm
	JL40	JUDKINS LEFT	4.0 cm
	JL50	JUDKINS LEFT	5.0 cm
	JL60	JUDKINS LEFT	6.0 cm
	JR35	JUDKINS RIGHT	3.5 cm
	JR40	JUDKINS RIGHT	4.0 cm
	JR50	JUDKINS RIGHT	5.0 cm
	JR60	JUDKINS RIGHT	6.0 cm
	MP25	Multipurpose	2.5 cm
	MP30	Multipurpose	3.0 cm
	MP35	Multipurpose	3.5 cm
	MP40	Multipurpose	4.0 cm
	PL15	Baby Judkins Left	1.5 cm
	PL20	Baby Judkins Left	2.0 cm
	PL25	Baby Judkins Left	2.5 cm
	PL30	Baby Judkins Left	3.0 cm
	PR15	Baby Judkins Right	1.5 cm
	PR20	Baby Judkins Right	2.0 cm
	PR25	Baby Judkins Right	2.5 cm
	PR30	Baby Judkins Right	3.0 cm
	RD30	3D-Right Modified	3.0 cm
	RD40	3D RC	4.0 cm
	SAL1	AL 1	small
	SAL2	AL 2	middle
	SL35	JUDKINS LEFT	3.5 cm
	SL40	JUDKINS LEFT	4.0 cm
	SL50	JL 5.0	5.0 cm

5-8	SP00	Straight Pigtail	—
	SP02	Straight Pigtail	Small Loop
	ST01	Straight (without soft tip)	—
	TIG1	Radial TIG	4.0 cm
	TIG2	Radial TIG 4.5	4.5 cm
	TR35	Radial TIG II 3.5	3.5 cm
	TR40	Radial TIG II 4.0	4.0 cm
	TR45	Radial TIG II 4.5	4.5 cm
	TR50	Radial TIG II 5.0	5.0 cm
9	Number of holes : Character : 0 1 2 4 6 8 Number : 0 1 2 4 6 8		
10	**Catheter length** Character 4 E 5 F 6 G 7 H 8 I 9 Length (cm) 40 45 50 55 60 65 70 75 80 85 90 Character J 0 K 1 L 2 N Length (cm) 95 100 105 110 115 120 125 * The maximum catheter length for the following tip shapes is 100 cm: 3D-Right Modified and 3D RC		
11	Braid cut length Q : 60 mm (For products whose braid cut length is not 60mm, the product code consists of 11 characters and the 11th character denotes the language for labeling.)		
12	**Languages used for the indications** M: Multi-language		

2) Visceral and cerebral use

Character number	Meaning of indication			
1-2	Product type RH : Radifocus® Optitorque™			
3	Destination * : for export (Manufactured by Terumo Co. Ashitaka factory) + / * : for export excluding Japan (Manufactured by Terumo Vietnam Co., Ltd)			
4	Indication of catheter use A : Visceral use, B : Cerebral use			
5-6	Tip shape Indication of tip configuration: these two digits together with digit 4 makes an unique code specific for each tip shape and number of side holes			
	Two digits	Tip shape	Tip curve length	Side holes
	Visceral use			
	AF	AAF	—	6
	B4	Cobra1 (C1)	Small	None
	B5	Cobra2 (C2)	Middle	None

5-6	B6	Cobra3 (C3)	Large	None
	BI	Cobra1 (C1)	Small	1
	C3	SHEPHERD HOOK	0.8cm	None
	C4	SHEPHERD HOOK	1.0cm	None
	D1	J Curve	7.0cm	None
	D4	J Curve	Large	None
	D5	J Curve	Middle	None
	D6	J Curve	Small	None
	E4	SIDEWINDER	1	None
	E5	SIDEWINDER	2	None
	E6	SIDEWINDER	3	None
	EC	MESENT	—	1
	ED	SIDEWINDER Type: S-J	1	None
	F1	Mikaelsson (1)	—	None
	G1	RLG	—	None
	G3	RH	—	None
	G4	RS	—	None
	G9	YASHIRO TYPE	—	None
	GF	RH Modified	—	None
	M7	Straight	—	None
	R9	RH CK TYPE	—	None
	UB	UFE Type 1	19 cm	None
	ZX	Straight	—	8
	Cerebral use			
	A1	Simmons/Sidewinder 1	Sim1	None
	A2	Simmons/Sidewinder 2	Sim2	None
	A3	Simmons/Sidewinder 3	Sim3	None
	B1	Hinck Headhunter 1	H1	None
	B2	HEADHUNTER	3	None
	B3	HEADHUNTER	4	None
	C1	NEWTON TECHNIQUE	1	None
	C2	NEWTON TECHNIQUE	2	None
	C3	NEWTON TECHNIQUE	3	None
	E1	Bentson-Hanafee-Wilson 1	JB1	None
	E2	Bentson-Hanafee-Wilson 2	JB2	None
	G1	Mani	—	None
	H1	Vertebral	—	None
	H8	Vertebral	—	2
	H9	Vertebral Bolia Mini Cath	—	None
	K9	Sliding Curve	—	None
	L1	BERENSTEIN	BL1	None
	R5	Hinck Headhunter 1	Short tip	None

5-6	R7	MEDULLAR II	Middle	None
	R8	MEDULLAR I	Small	None
	R9	MEDULLAR III	Large	None

7	Outer diameter of catheter (indication on labelling) 4 : 4 Fr. (1.40 mm), 5 : 5 Fr. (1.70 mm)
8	**Availability of stopcock** 1 : without stopcock
9-10	**Catheter length** Character 02 03 04 05 06 0G 07 0H 08 0I 09 Length (cm) 20 30 40 50 60 65 70 75 80 85 90 Character 0J 10 1A 11 1B 12 1C Length (cm) 95 100 105 110 115 120 125
11	**Languages used for the indications** M: Multi-language

DECLARATION OF CONFORMITY

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

being the manufacturer of:

RADIFOCUS® OPTITORQUE™

Product: **Catheter for Angiography**
(See Appendix A for related product codes)

declare that the above product of Class III 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.3 (Registration No: HD 60134707 0001) and Annex II.4 (Registration No: ID 60149181 0001), under the supervision of TÜV Rheinland LGA Products GmbH as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0197.

Leuven, 12.10.2022
(place and date of issue)

K. Verhaert
Vice President Quality,
Regulatory and Vigilance
TERUMO EUROPE N.V.

Appendix A – Related product codes

The product code is composed of 11 digits maximum and explained as follows:

Thoracic use

1	2	3	4	5	6	7	8	9	10	11
R	H	Radifocus Optitorque								
Production site		-	Terumo Europe							
Catheter size O.D.			**4**	4 Fr. / 1.40 mm						
			5	5 Fr. / 1.70 mm						
			6	6 Fr. / 2.00 mm						

Indication of tip configuration					Tip Shape	Tip curve length
	A	**L**	**1**	**0**	Amplatz Left	Small
	A	**L**	**2**	**0**	Amplatz Left	Middle
	A	**L**	**3**	**0**	Amplatz Left	Large
	A	**P**	**4**	**5**	Angled Pigtail 145°	5.5 cm
	A	**P**	**5**	**5**	Angled Pigtail 155°	5.5 cm
	A	**P**	**6**	**5**	Angled Pigtail 165°	5.5 cm
	A	**P**	**R**	**2**	Angled Pigtail Round Type 155°	2.0 cm
	A	**R**	**1**	**0**	Amplatz Right	Small
	A	**R**	**2**	**0**	Amplatz Right	Middle
	A	**R**	**3**	**0**	Amplatz Right	Large
	A	**R**	**J**	**P**	Amplatz Right Type JP	Small
	A	**R**	**R**	**5**	Amplatz Modified Type NTR r5	-
	A	**R**	**R**	**C**	Amplatz Modified Type NTR	-
	B	**L**	**K**	**4**	Radial BLK	-
	B	**P**	**I**	**M**	Internal Mammary (Round tip)	-
	B	**P**	**I**	**N**	Internal Mammary	-
	B	**P**	**I**	**R**	Internal Mammary (short tip)	-
	B	**P**	**J**	**L**	Bypass Judkins Left	-
	B	**P**	**J**	**P**	Internal Mammary type JP	-
	B	**P**	**J**	**R**	Bypass Judkins Right	-
	B	**P**	**R**	**A**	Internal Mammary Type RA	-
	B	**P**	**R**	**B**	Internal Mammary Type RB	-
	B	**R**	**5**	**5**	Hinck Headhunter 1 (short tip)	-
	B	**U**	**3**	**5**	Backup Left	3.5 cm
	C	**A**	**S**	**1**	Castillo	Small
	C	**A**	**S**	**2**	Castillo	Middle
	C	**A**	**S**	**3**	Castillo	Large
	C	**L**	**2**	**5**	Judkins Left	2.5 cm
	C	**L**	**3**	**5**	Judkins Left	3.5 cm
	C	**L**	**4**	**0**	Judkins Left	4.0 cm
	C	**L**	**4**	**5**	Judkins Left	4.5 cm
	C	**L**	**5**	**0**	Judkins Left	5.0 cm
	C	**L**	**6**	**0**	Judkins Left	6.0 cm
	C	**R**	**2**	**5**	Judkins Right	2.5 cm
	C	**R**	**3**	**5**	Judkins Right	3.5 cm
	C	**R**	**4**	**0**	Judkins Right	4.0 cm
	C	**R**	**4**	**1**	Judkins Right	4.0 cm
	C	**R**	**4**	**5**	Judkins Right	4.5 cm
	C	**R**	**5**	**0**	Judkins Right	5.0 cm
	C	**R**	**6**	**0**	Judkins Right	6.0 cm
	H	**L**	**4**	**0**	Radial L-40	4.0 cm
	H	**R**	**4**	**0**	Radial R-40	4.0 cm
	J	**L**	**3**	**5**	Judkins Left (Original Shape)	3.5 cm

1	2	3	4	5	6	7	8	9	10	11
				J	L	4	0	Judkins Left (Original Shape)		4.0 cm
				J	L	5	0	Judkins Left (Original Shape)		5.0 cm
				J	R	3	5	Judkins Right (Original Shape)		3.5 cm
				J	R	4	0	Judkins Right (Original Shape)		4.0 cm
				J	R	5	0	Judkins Right (Original Shape)		5.0 cm
				J	R	6	0	Judkins Right (Original Shape)		6.0 cm
				K	T	4	0	Modified JL-4.0 Type KT		4.0 cm
				M	P	1	5	Multipurpose		1.5 cm
				M	P	2	5	Multipurpose		2.5 cm
				M	P	3	0	Multipurpose		3.0 cm
				M	P	3	1	Multipurpose (3.0 cm) Type EL GAMAL I		Small
				M	P	3	5	Multipurpose (3.5 cm)		3.5 cm
				M	P	4	0	Multipurpose (4.0 cm)		4.0 cm
				M	P	4	1	Multipurpose (4.0 cm) Type EL GAMAL II		Medium
				S	P	0	0	Straight Pigtail		-
				S	P	G	1	Straight Pigtail		Large
				S	T	0	0	Straight (with soft tip)		-
				S	T	0	1	Straight (without soft tip)		-
				S	A	L	1	Amplatz Left (short tip)		Small
				S	A	L	2	Amplatz Left (short tip)		Middle
				S	A	R	1	Amplatz Right(short tip)		Small
				S	A	R	2	Amplatz Right (short tip)		Middle
				S	L	3	5	Judkins Left (Original A Type)		3.5 cm
				S	L	4	0	Judkins Left (Original A Type)		4.0 cm
				S	R	4	0	Judkins Right (Original A Type)		4.0 cm
				T	I	G	1	Brachial Type		4.0 cm
				T	R	3	5	Radial TIG II 3.5		3.5 cm
				T	R	4	0	Radial TIG II 4.0		4.0 cm
				T	R	4	5	Radial TIG II 4.5		4.5 cm
				T	R	5	0	Radial TIG II 5.0		5.0 cm
Number of side holes								**0 ~ 9**	0 to 9 side holes	
Catheter length									**6**	60 cm
									G	65 cm
									7	70 cm
									8	80 cm
									9	90 cm
									0	100 cm
									1	110 cm
Languages used for the indications								Multi-language		**M**

Visceral and cerebral use

1	2	3	4	5	6	7	8	9	10	11
R	H	RadiFocus Optitorque								
Production site		-	Terumo Europe							
Indication of catheter use & structure			**A**	Visceral use						
			B	Cerebral use						
Indication of tip configuration						Tip shape			Tip curve length	Side holes
				A in position 4						
				A	**2**	Renal			-	None
				B	**4**	Cobra 1 (C1)			Small	None
				B	**5**	Cobra 2 (C2)			Middle	None
				B	**6**	Cobra 3 (C3)			Large	None
				B	**P**	Headhunter			9.5 cm	None
				C	**3**	Shephard Hook			0.8 cm	None
				C	**4**	Shephard Hook			1.0 cm	None
				D	**1**	J Curve			7.0 cm	None
				D	**4**	J Curve			Large	None
				D	**5**	J Curve			Middle	None
				D	**6**	J Curve			Small	None
				E	**4**	Sidewinder			1 cm	None
				E	**5**	Sidewinder			2 cm	None
				E	**6**	Sidewinder			3 cm	None
				E	**D**	Sidewinder Type S-J			1 cm	None
				F	**1**	Mikaelsson (1)			-	None
				P	**C**	BPH			19 cm	None
				U	**B**	UFE			19 cm	None
				B in position 4						
				A	**1**	Simmons/ Sidewinder 1			Sim 1	None
				A	**2**	Simmons/ Sidewinder 2			Sim 2	None
				A	**3**	Simmons/ Sidewinder 3			Sim 3	None
				B	**1**	Hinck Headhunter 1			H1	None
				B	**2**	Hinck Headhunter 3			H3	None
				B	**3**	Headhunter			4	None
				C	**1**	Newton Technique			1	None
				C	**2**	Newton Technique			2	None
				C	**3**	Newton Technique			3	None
				E	**1**	Bentson-Hanafee-Wilson 1			JB1	None
				E	**2**	Bentson-Hanafee-Wilson 2			JB2	None
				G	**1**	Mani			-	None
				H	**1**	Vertebral			-	None
				H	**8**	Vertebral			-	2
				H	**9**	Vertebral			Bolia Minicath	None
				H	**B**	Vertebral (short tip)			-	None
				L	**1**	Berenstein			BL1	None
				R	**5**	Hinck Headhunter 1 (short tip)			H1	None
				R	**7**	Medullar II			Middle	None
				R	**8**	Medullar I			Small	None
				R	**9**	Medullar III			Large	None
Outer diameter of catheter						**4**	4 Fr. / 1.40 mm			
						5	5 Fr. / 1.70 mm			
Indication of stopcock							**1**	Without two-way stopcock		
Catheter length								**0**	**2**	20 cm
								0	**G**	65 cm

1	2	3	4	5	6	7	8	9	10	11
								0	**7**	70 cm
								0	**8**	80 cm
								0	**9**	90 cm
								1	**0**	100 cm
								1	**1**	110 cm
Languages used for the indications								Multilingual		**M**