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. 1 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: Catheter Introducer

Model: RADIFOCUS Introducer II

RS*R60N10MQ	RS*B40G10SQ	RS*B60N10SQ	RS*B80N25AQ	RS*A40G10SQ
RS*R70N10MQ	RS*B40K10SQ	RS*B60N25AQ	RS*B90N10SQ	RS*A50K10AQ
RS*R80N10MQ	RS*B50N10AQ	RS*B70N10SQ	RS*B90N25AQ	RS*A50K10SQ
RS*R90N10MQ	RS*B50N10SQ	RS*B70N25AQ	RS*B11N10SQ	RS*A60K10AQ
RS*B40K10AQ	RS*B50N25AQ	RS*B80N10SQ	RS*A40K10AQ	RS*A70K10SQ
RS*A80K10SQ				
RS*A90K10SQ				
RS*A10K10SQ				
RS*A11K10SQ				

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 _____

Digitally signed by Grabazei Alexandru
Date: 2023.10.13 15:31:28 EEST
Reason: MoldSign Signature
Location: Moldova

Tabelul de recepționare a notificării

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

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: Catheter Introducer

Model: RADIFOCUS Introducer II

RS*R60N10MQ	RS*B40G10SQ	RS*B60N10SQ	RS*B80N25AQ	RS*A40G10SQ
RS*R70N10MQ	RS*B40K10SQ	RS*B60N25AQ	RS*B90N10SQ	RS*A50K10AQ
RS*R80N10MQ	RS*B50N10AQ	RS*B70N10SQ	RS*B90N25AQ	RS*A50K10SQ
RS*R90N10MQ	RS*B50N10SQ	RS*B70N25AQ	RS*B11N10SQ	RS*A60K10AQ
RS*B40K10AQ	RS*B50N25AQ	RS*B80N10SQ	RS*A40K10AQ	RS*A70K10SQ
RS*A80K10SQ				
RS*A90K10SQ				
RS*A10K10SQ				
RS*A11K10SQ				

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

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®

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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

TERUMO

No.DOC-DQ010- 0245/DOC-DQ010-0821
Rev.22

DECLARATION OF CONFORMITY

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

being the manufacturer of:

RADIFOCUS Introducer II

Product : Catheter Introducer

declare that the above products of **Class IIa** 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, 2 and 11, 3(a) of the Directive, relating to the "Full quality assurance" set out in Annex II, and by certification of Annex II, excluding Section 4 under the supervision of TÜV Rheinland LGA Products GmbH (Registration No.: HD 60145252 0001), 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, July 27, 2023
(place and date of issue)

Toshio Nakashima
General Manager
Quality Assurance Department
TERUMO CORPORATION

Appendix A - List of Code Number Structure

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

Character number	Characters & Meaning
1, 2	Product name RS: Introducer kit RM: Introducer kit containing hydrophilic polymer-coated sheath.
3	Destination *: for export
4	Kit contents A : Sheath, Dilator, Mini guide wire, Syringe, Entry needle (SurfloFlash), Scalpel[*1], (Guide inserter[*2]) B : Sheath, Dilator, Mini guide wire, (Guide inserter[*2]) C : Sheath, Dilator E : Sheath, Dilator, Mini guide wire, Entry needle (SurfloFlash), (Guide inserter[*2]) G : Sheath, Dilator, Mini guide wire, Scalpel[*1] (Guide inserter[*2]) H : Dilator J : Sheath, Dilator, Scalpel[*1] K : Sheath, Dilator, Mini guide wire, Syringe, Entry needle (metallic needle), Scalpel[*1], (Guide inserter[*2]) L : Sheath, Dilator, Syringe, Entry needle (SurfloFlash), Scalpel[*1] M : Sheath, Dilator, Entry needle (SurfloFlash), Scalpel[*1] N : Sheath, Dilator, Mini guide wire, Syringe, Scalpel[*1], (Guide inserter[*2]) P : Sheath, Dilator, Mini guide wire, Syringe, Entry needle (SurfloFlash), (Guide inserter[*2]) Q : Dilator, Mini guide wire, (Guide inserter[*2]) R : Sheath, Dilator, Mini guide wire, Entry needle (metallic needle / Metallic Entry Needle improved product), (Guide inserter[*2]) S : Sheath, Dilator, Mini guide wire, Entry needle (SurfloFlash), Scalpel[*1], (Guide inserter[*2]) W : Mini guide wire [*1]: not contained in the export specifications [*2]: contained when the mini guide wire has an angled tip or a J tip.

<table>
<tr><th>Character number</th><th>Characters & Meaning</th></tr>
<tr><td>5-6</td><td>Sheath Size (w/o hydrophilic polymer coating)
Characters: 40 50 55 60 65 70 75 80 85 90 10 11 00
Size: 4.0 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 10.0 11.0 no sheath
Sheath Size (with hydrophilic polymer coating)
Characters: F4 F5 F6 F7
Size: 4.0 5.0 6.0 7.0</td></tr>
<tr><td>7</td><td>Mini guide wire OD, Dilator ID, Size of Enrty needle (length of projecting portion of dilator is 25mm)
Standard Type (the items with their product code starting with RS*)
<table>
<tr><td colspan="2" rowspan="2"></td><td colspan="5">Mini guide wire diameter/ Dilator inner diameter</td><td rowspan="2">Type of Surflo</td></tr>
<tr><td>0.018”</td><td>0.021”</td><td>0.025”</td><td>0.035”</td><td>0.038”</td></tr>
<tr><td rowspan="4">Type of scalpel and tray</td><td>b-type</td><td>A</td><td>D</td><td>G</td><td>K</td><td>N</td><td rowspan="2">Standard</td></tr>
<tr><td>a-type</td><td>B</td><td>E</td><td>H</td><td>L</td><td>P</td></tr>
<tr><td>b-type</td><td>C</td><td>F</td><td>J</td><td>M</td><td>Q</td><td rowspan="2">With adapter</td></tr>
<tr><td>a-type</td><td>V</td><td>W</td><td>X</td><td>Y</td><td>Z</td></tr>
<tr><td colspan="2">Entry needle size</td><td>22G×1”</td><td>22G×1”</td><td>20G×2”</td><td>18G×2 1/2”</td><td>16G×2 1/2”</td><td></td></tr>
<tr><td colspan="2">metallic needle size</td><td>---</td><td>---</td><td>---</td><td>18G×2 3/4”</td><td>18G×2 3/4”</td><td></td></tr>
</table>
Kit containing a hydrophilic polymer-coated sheath (the items with their product code starting with RM):
<table>
<tr><th colspan="2" rowspan="2"></th><th colspan="5">Mini guide wire diameter/ Dilator inner diameter</th><th rowspan="2">Type of Surflo</th></tr>
<tr><th>0.018”</th><th>0.021”</th><th>0.025”</th><th>0.035”</th><th>0.038”</th></tr>
<tr><td rowspan="4">Type of scalpel and tray</td><td>b-type</td><td>A</td><td>D</td><td>G</td><td>K</td><td>N</td><td rowspan="2">With adapter</td></tr>
<tr><td>a-type</td><td>B</td><td>E</td><td>H</td><td>L</td><td>P</td></tr>
<tr><td>b-type</td><td>C</td><td>F</td><td>J</td><td>M</td><td>Q</td><td rowspan="2">Standard</td></tr>
<tr><td>a-type</td><td>V</td><td>W</td><td>X</td><td>Y</td><td>Z</td></tr>
<tr><td colspan="2">Entry needle size</td><td>22G×1”</td><td>22G×1”</td><td>20G×2”</td><td>18G×2 1/2”</td><td>16G×2 1/2”</td><td></td></tr>
<tr><td colspan="2">metallic needle size</td><td>---</td><td>Metallic Entry Needle improved product 21G×1 2/5”</td><td>Metallic Entry Needle improved product 20G×1 2/5”</td><td>18G×2 3/4”</td><td>18G×2 3/4”</td><td></td></tr>
</table></td></tr>
</table>

Character number	Characters & Meaning
8-9	Length of sheath 05 ~: 50 mm ~
10	Type of mini guide wire A: Plastic, Angled B: Plastic, Angled, 4mm of tip cut E: Straight E F: Flex, Angled H: Short tapered, short angle J: Plastic, 3mm J K: Stiff, Angled M: Spring, J N: No mini guide wire contained. P: Spring, Straight S: Plastic, Straight V: Plastic, 1.5mm J-angle Y: Flex, Straight
11	Packaging Q: Tray package (Multi-language) R: Pouch package (Multi-language)
12	Reserved 1: With scalpel. 5: Inner diameter of dilator at distal end: 0.038", Outer diameter of mini guide wire: 0.035" Z: Entry needle: 20Gx2"→20Gx1 1/4" Length of mini guide wire: 80cm→45cm, scalpel contained. W: Entry needle: 20Gx2"→20Gx1 1/4", scalpel contained.

Appendix A - List of Code Number Structure

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

<table>
<tr><th>Character number</th><th>Characters & Meaning</th></tr>
<tr><td>1, 2</td><td>Product name
RS: Introducer kit
RM: Introducer kit containing hydrophilic polymer-coated sheath</td></tr>
<tr><td>3</td><td>Destination
+/ ＊: Manufactured by TVC for worldwide excluding Japan</td></tr>
<tr><td>4</td><td>Kit contents
A : Sheath, Dilator, Mini guide wire, Syringe, Entry needle (SurfloFlash), Scalpel*1, (Guide inserter*2)
B : Sheath, Dilator, Mini guide wire, (Guide inserter*2)
C : Sheath, Dilator
R : Sheath, Dilator, Mini guide wire, Entry needle (metallic needle), (Guide inserter*2)
*1: not contained in the export specification
*2: contained when the mini guide wire has an angled tip or a J tip.</td></tr>
<tr><td>5-6</td><td>Sheath Size (Fr) (w/o hydrophilic polymer coating)
<table>
<tr><td>Characters</td><td>40</td><td>50</td><td>60</td><td>70</td><td>80</td></tr>
<tr><td>Size</td><td>4.0</td><td>5.0</td><td>6.0</td><td>7.0</td><td>8.0</td></tr>
</table>
Sheath Size (Fr) (with hydrophilic polymer coating)
<table>
<tr><td>Characters</td><td>F5</td><td>F6</td></tr>
<tr><td>Size</td><td>5.0</td><td>6.0</td></tr>
</table></td></tr>
<tr><td>7</td><td>Mini guide wire OD, Dilator ID, Size of Enrty needle (length of projecting portion of dilator is 25mm)
Standard Type (the items with their product code starting with RS*)
<table>
<tr><td></td><td colspan="3">Mini guide wire diameter/ Dilator inner diameter</td><td>Type of Surflo</td></tr>
<tr><td></td><td>0.025”</td><td>0.035”</td><td>0.038”</td><td></td></tr>
<tr><td>Type of scalpel and tray</td><td>G</td><td>K</td><td>N</td><td>Standard</td></tr>
<tr><td>Entry needle size</td><td>20G×2”</td><td>18G×2 1/2”</td><td>16G×2 1/2”</td><td></td></tr>
<tr><td>Metallic needle size</td><td>---</td><td>18G×2 3/4”</td><td>18G×2 3/4”</td><td></td></tr>
</table>
Kit containing a hydrophilic polymer-coated sheath (the items with their product code starting with RM*)
<table>
<tr><td></td><td colspan="3">Mini guide wire diameter/ Dilator inner diameter</td><td>Type of Surflo</td></tr>
<tr><td></td><td>0.021”</td><td>0.025”</td><td>0.035”</td><td></td></tr>
<tr><td>Type of scalpel and tray</td><td>---</td><td>G</td><td>---</td><td>With adapter</td></tr>
<tr><td></td><td>F</td><td>J</td><td>M</td><td>Standard</td></tr>
<tr><td>Entry needle size</td><td>---</td><td>20G×2”</td><td>---</td><td></td></tr>
<tr><td>Metallic needle size</td><td>Metallic Entry Needle improved product 21G×1 2/5”</td><td>Metallic Entry Needle improved product 21G×1 2/5”</td><td>---</td><td></td></tr>
</table></td></tr>
<tr><td>8-9</td><td>Length of sheath
00 : no sheath</td></tr>
</table>

	05~ : 50mm~~
10	Type of mini guide wire A: Plastic, Angled M: Spring, J N: No mini guide wire contained. P: Spring, Straight S: Plastic, Straight H: Short tapered, short angle
11	Packaging Q: Tray package (Multi-language #, Chinese) R: Pouch package (Multi-language #, Chinese)
12	Reserved 1: With scalpel. 5: Inner diameter of dilator at distal end: 0.038", Outer diameter of mini guide wire: 0.035" Z: Entry needle: 20Gx2"→20Gx1 1/4" Length of mini guide wire: 80cm→45cm, scalpel contained. W: Entry needle: 20Gx2" →20Gx1 1/4" , scalpel contained.

TERUMO

No.DOC-DQ010- 0245/DOC-DQ010-0821
Rev.22

DECLARATION OF CONFORMITY

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

being the manufacturer of:

RADIFOCUS Introducer II

Product : Catheter Introducer

declare that the above products of **Class IIa** 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, 2 and 11, 3(a) of the Directive, relating to the "Full quality assurance" set out in Annex II, and by certification of Annex II, excluding Section 4 under the supervision of TÜV Rheinland LGA Products GmbH (Registration No.: HD 60145252 0001), 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, July 27, 2023
(place and date of issue)

Toshio Nakashima
General Manager
Quality Assurance Department
TERUMO CORPORATION

Appendix A - List of Code Number Structure

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

Character number	Characters & Meaning
1, 2	Product name RS: Introducer kit RM: Introducer kit containing hydrophilic polymer-coated sheath.
3	Destination *: for export
4	Kit contents A : Sheath, Dilator, Mini guide wire, Syringe, Entry needle (SurfloFlash), Scalpel[*1], (Guide inserter[*2]) B : Sheath, Dilator, Mini guide wire, (Guide inserter[*2]) C : Sheath, Dilator E : Sheath, Dilator, Mini guide wire, Entry needle (SurfloFlash), (Guide inserter[*2]) G : Sheath, Dilator, Mini guide wire, Scalpel[*1] (Guide inserter[*2]) H : Dilator J : Sheath, Dilator, Scalpel[*1] K : Sheath, Dilator, Mini guide wire, Syringe, Entry needle (metallic needle), Scalpel[*1], (Guide inserter[*2]) L : Sheath, Dilator, Syringe, Entry needle (SurfloFlash), Scalpel[*1] M : Sheath, Dilator, Entry needle (SurfloFlash), Scalpel[*1] N : Sheath, Dilator, Mini guide wire, Syringe, Scalpel[*1], (Guide inserter[*2]) P : Sheath, Dilator, Mini guide wire, Syringe, Entry needle (SurfloFlash), (Guide inserter[*2]) Q : Dilator, Mini guide wire, (Guide inserter[*2]) R : Sheath, Dilator, Mini guide wire, Entry needle (metallic needle / Metallic Entry Needle improved product), (Guide inserter[*2]) S : Sheath, Dilator, Mini guide wire, Entry needle (SurfloFlash), Scalpel[*1], (Guide inserter[*2]) W : Mini guide wire [*1]: not contained in the export specifications [*2]: contained when the mini guide wire has an angled tip or a J tip.

<table>
<tr><th>Character number</th><th>Characters & Meaning</th></tr>
<tr><td>5-6</td><td>Sheath Size (w/o hydrophilic polymer coating)
Characters: 40 50 55 60 65 70 75 80 85 90 10 11 00
Size: 4.0 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 10.0 11.0 no sheath
Sheath Size (with hydrophilic polymer coating)
Characters: F4 F5 F6 F7
Size: 4.0 5.0 6.0 7.0</td></tr>
<tr><td>7</td><td>Mini guide wire OD, Dilator ID, Size of Enrty needle (length of projecting portion of dilator is 25mm)
Standard Type (the items with their product code starting with RS*)
<table>
<tr><td colspan="2" rowspan="2"></td><td colspan="5">Mini guide wire diameter/ Dilator inner diameter</td><td rowspan="2">Type of Surflo</td></tr>
<tr><td>0.018”</td><td>0.021”</td><td>0.025”</td><td>0.035”</td><td>0.038”</td></tr>
<tr><td rowspan="4">Type of scalpel and tray</td><td>b-type</td><td>A</td><td>D</td><td>G</td><td>K</td><td>N</td><td rowspan="2">Standard</td></tr>
<tr><td>a-type</td><td>B</td><td>E</td><td>H</td><td>L</td><td>P</td></tr>
<tr><td>b-type</td><td>C</td><td>F</td><td>J</td><td>M</td><td>Q</td><td rowspan="2">With adapter</td></tr>
<tr><td>a-type</td><td>V</td><td>W</td><td>X</td><td>Y</td><td>Z</td></tr>
<tr><td colspan="2">Entry needle size</td><td>22G×1”</td><td>22G×1”</td><td>20G×2”</td><td>18G×2 1/2”</td><td>16G×2 1/2”</td><td></td></tr>
<tr><td colspan="2">metallic needle size</td><td>---</td><td>---</td><td>---</td><td>18G×2 3/4”</td><td>18G×2 3/4”</td><td></td></tr>
</table>
Kit containing a hydrophilic polymer-coated sheath (the items with their product code starting with RM):
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<tr><td colspan="2">metallic needle size</td><td>---</td><td>Metallic Entry Needle improved product 21G×1 2/5”</td><td>Metallic Entry Needle improved product 20G×1 2/5”</td><td>18G×2 3/4”</td><td>18G×2 3/4”</td><td></td></tr>
</table></td></tr>
</table>

Character number	Characters & Meaning
8-9	Length of sheath 05 ~: 50 mm ~
10	Type of mini guide wire A: Plastic, Angled B: Plastic, Angled, 4mm of tip cut E: Straight E F: Flex, Angled H: Short tapered, short angle J: Plastic, 3mm J K: Stiff, Angled M: Spring, J N: No mini guide wire contained. P: Spring, Straight S: Plastic, Straight V: Plastic, 1.5mm J-angle Y: Flex, Straight
11	Packaging Q: Tray package (Multi-language) R: Pouch package (Multi-language)
12	Reserved 1: With scalpel. 5: Inner diameter of dilator at distal end: 0.038", Outer diameter of mini guide wire: 0.035" Z: Entry needle: 20Gx2"→20Gx1 1/4" Length of mini guide wire: 80cm→45cm, scalpel contained. W: Entry needle: 20Gx2"→20Gx1 1/4", scalpel contained.

Appendix A - List of Code Number Structure

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

<table>
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<tr><td>1, 2</td><td>Product name
RS: Introducer kit
RM: Introducer kit containing hydrophilic polymer-coated sheath</td></tr>
<tr><td>3</td><td>Destination
+/ ＊: Manufactured by TVC for worldwide excluding Japan</td></tr>
<tr><td>4</td><td>Kit contents
A : Sheath, Dilator, Mini guide wire, Syringe, Entry needle (SurfloFlash), Scalpel*1, (Guide inserter*2)
B : Sheath, Dilator, Mini guide wire, (Guide inserter*2)
C : Sheath, Dilator
R : Sheath, Dilator, Mini guide wire, Entry needle (metallic needle), (Guide inserter*2)
*1: not contained in the export specification
*2: contained when the mini guide wire has an angled tip or a J tip.</td></tr>
<tr><td>5-6</td><td>Sheath Size (Fr) (w/o hydrophilic polymer coating)
<table>
<tr><td>Characters</td><td>40</td><td>50</td><td>60</td><td>70</td><td>80</td></tr>
<tr><td>Size</td><td>4.0</td><td>5.0</td><td>6.0</td><td>7.0</td><td>8.0</td></tr>
</table>
Sheath Size (Fr) (with hydrophilic polymer coating)
<table>
<tr><td>Characters</td><td>F5</td><td>F6</td></tr>
<tr><td>Size</td><td>5.0</td><td>6.0</td></tr>
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Standard Type (the items with their product code starting with RS*)
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<tr><td>Type of scalpel and tray</td><td>G</td><td>K</td><td>N</td><td>Standard</td></tr>
<tr><td>Entry needle size</td><td>20G×2”</td><td>18G×2 1/2”</td><td>16G×2 1/2”</td><td></td></tr>
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Kit containing a hydrophilic polymer-coated sheath (the items with their product code starting with RM*)
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<tr><td></td><td>0.021”</td><td>0.025”</td><td>0.035”</td><td></td></tr>
<tr><td>Type of scalpel and tray</td><td>---</td><td>G</td><td>---</td><td>With adapter</td></tr>
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00 : no sheath</td></tr>
</table>

	05~ : 50mm~~
10	Type of mini guide wire A: Plastic, Angled M: Spring, J N: No mini guide wire contained. P: Spring, Straight S: Plastic, Straight H: Short tapered, short angle
11	Packaging Q: Tray package (Multi-language #, Chinese) R: Pouch package (Multi-language #, Chinese)
12	Reserved 1: With scalpel. 5: Inner diameter of dilator at distal end: 0.038", Outer diameter of mini guide wire: 0.035" Z: Entry needle: 20Gx2"→20Gx1 1/4" Length of mini guide wire: 80cm→45cm, scalpel contained. W: Entry needle: 20Gx2" →20Gx1 1/4" , scalpel contained.