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

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

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

nr. 2 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 Transradial Kit**

| | | |
|---|---|---|
| RT-R40A07PQ | RT-R50A07PQ | RT-R60A07PQ |
| RT-R40G07PQ | RT-R50G07PQ | RT-R60G07PQ |
| RT-R40A10PQ | RT-R50A10PQ | RT-R60A10PQ |
| RT-R40D10PQ | RT-R50D10PQ | RT-R60D10PQ |
| RT-R40G10PQ | RT-R50G10PQ | RT-R60G10PQ |
| | | RT-R70D10PQ |

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

Digitally signed by Grabazei Alexandru
Date: 2023.10.13 15:31:37 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: Catheter Introducer

## Model: RADIFOCUS Introducer II Transradial Kit

| | | |
|---|---|---|
| RT-R40A07PQ | RT-R50A07PQ | RT-R60A07PQ |
| RT-R40G07PQ | RT-R50G07PQ | RT-R60G07PQ |
| RT-R40A10PQ | RT-R50A10PQ | RT-R60A10PQ |
| RT-R40D10PQ | RT-R50D10PQ | RT-R60D10PQ |
| RT-R40G10PQ | RT-R50G10PQ | RT-R60G10PQ |
| | | RT-R70D10PQ |

**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 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® Prüf- und Zertifizierungsstelle

**Date:** 2020-04-21

Dipl.-Ing. (FH) D. Wiedemuth

# DECLARATION OF CONFORMITY

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

being the manufacturer of:

## RADIFOCUS® INTRODUCER II
## (Transradial Kit)

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

declare that the above product of Class IIa 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), 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, 02.11.2022
(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 12 digits maximum and explained as follows:

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **R** | **T** | Radifocus Introducer II Transradial Access | | | | | | | | | |
| **Production site** | | **-** | Terumo Europe N.V. | | | | | | | | |
| **Indication of kit compostion** | | | **R** | Sheath, Dilator, Spring guide wire and metallic entry needle | | | | | | | |
| **Size of sheath in Fr** | | | | **4** | **0** | 4 Fr | | | | | |
| | | | | **5** | **0** | 5 Fr | | | | | |
| | | | | **6** | **0** | 6 Fr | | | | | |
| | | | | **7** | **0** | 7 Fr | | | | | |
| **Dilator I.D., distal tip length (difference of Dilator / sheath assembly), and type of metallic needle** | | | | | | **A** | 25 | | 0.018" | | 22G x 35 mm |
| | | | | | | **D** | 25 | | 0.021" | | 21G x 35 mm |
| | | | | | | **G** | 25 | | 0.025" | | 20G x 35 mm |
| **Length of the sheath** | | | | | | | **0** | **7** | 70 mm | | |
| | | | | | | | **1** | **0** | 100 mm | | |
| **Mini spring guide wire type** | | | | | | | | | **N** | No guide wire | |
| | | | | | | | | | **P** | Straight, fixed core, uncoated, distal end flexible | |
| **Packaging** | | | | | | | | | | **Q** | Tray pack (Multi language) |
| **Special product indication: alphanumerical digit to distinguish from standard items** | | | | | | | | | | | **X** |