



**Terumo Europe NV  
Emerging Market Division**

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**To: Whom It May Concern**

Ref: 2024/016/IS/MI

Leuven, January 31, 2024

**Letter of Authorization**

We, being the company-manufacturer **Terumo Europe N.V. (Belgium)**, with a manufacturing facility located at Interleuvenlaan 40, 3001, Leuven, 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 Interventional B.V., MicroVention Europe, MicroVention Inc** and **Kaneka Corporation**, hereby appoint following company (hereinafter - "Company"):

**F.C.P.C. "DataControl" S.R.L.**

17/6 N. Testimiteanu street,  
MD-2025 Chisinau  
Republic of Moldova

as authorized representative in correspondence with the conditions of either Medical Devices Directive 93/42/EEC or Medical Devices Regulation (EU) 2017/745<sup>1</sup> of the 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\***  
**Croserio 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\***

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<sup>1</sup> All products indicated with \* are currently CE marked in compliance with MDD (EU) 93/42/EEC with many of them scheduled to transition into MDR (EU) 2017/745. The other products are currently already CE marked in compliance with MDR (EU) 2017/745, so potentially these will already be supplied as such to Moldova.

Navicross Support Catheter\*  
Occlusafe Temporary Occlusion Balloon Catheter  
Outlook Angiographic Catheter\* (Terumo Corporation and Terumo Europe N.V.)  
Progreat Micro Catheter System (Terumo Corporation and Terumo Clinical Supply)  
Radifocus Glidecath Angiographic Catheter\* (Terumo Corporation and Terumo Europe N.V.)  
Radifocus Guide Wire GT with Gold Coil\*  
Radifocus Guide Wire M\* (Terumo Corporation and Terumo Europe N.V.)  
Radifocus Guide Wire M Non-Vascular  
RADIFOCUS® Glidewire Advantage™  
RADIFOCUS® Glidewire Advantage™ Track\*  
Radifocus Obturator\*  
Radifocus Torque Device  
Radifocus Vessel Dilator\*  
Radifocus OPTITORQUE Angiographic Catheter\* (Terumo Corporation and Terumo Europe N.V.)  
Radifocus Introducer II (Transradial Kit)\*  
Radifocus Introducer II\* (Terumo Corporation and Terumo Europe N.V.)  
Roadsaver Carotid Artery Stent\*  
Runthrough® NS Extension Wire PTCA Guide Wire  
Runthrough® NS PTCA Guide Wire  
Ryujin Plus PTCA dilatation catheter (RX)  
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

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

This authorization letter is valid for a period of 5 /five/ years from the date of issue, unless revoked earlier by Terumo Europe N.V.

For and behalf of Terumo Europe N.V.:

DocuSigned by:  
*Valérie Boydens*  
 Signer Name: Valérie Boydens  
Signing Reason: I approve this document  
Signing Time: 31-Jan-2024 | 09:55 CET  
6B3DF6DDB3AF496B9561A701281A11CA  
**Valérie Boydens**

Director Regulatory Affairs  
Terumo Europe N.V.