



**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) 2017/745¹ 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*

¹ 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
Ryuji 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.