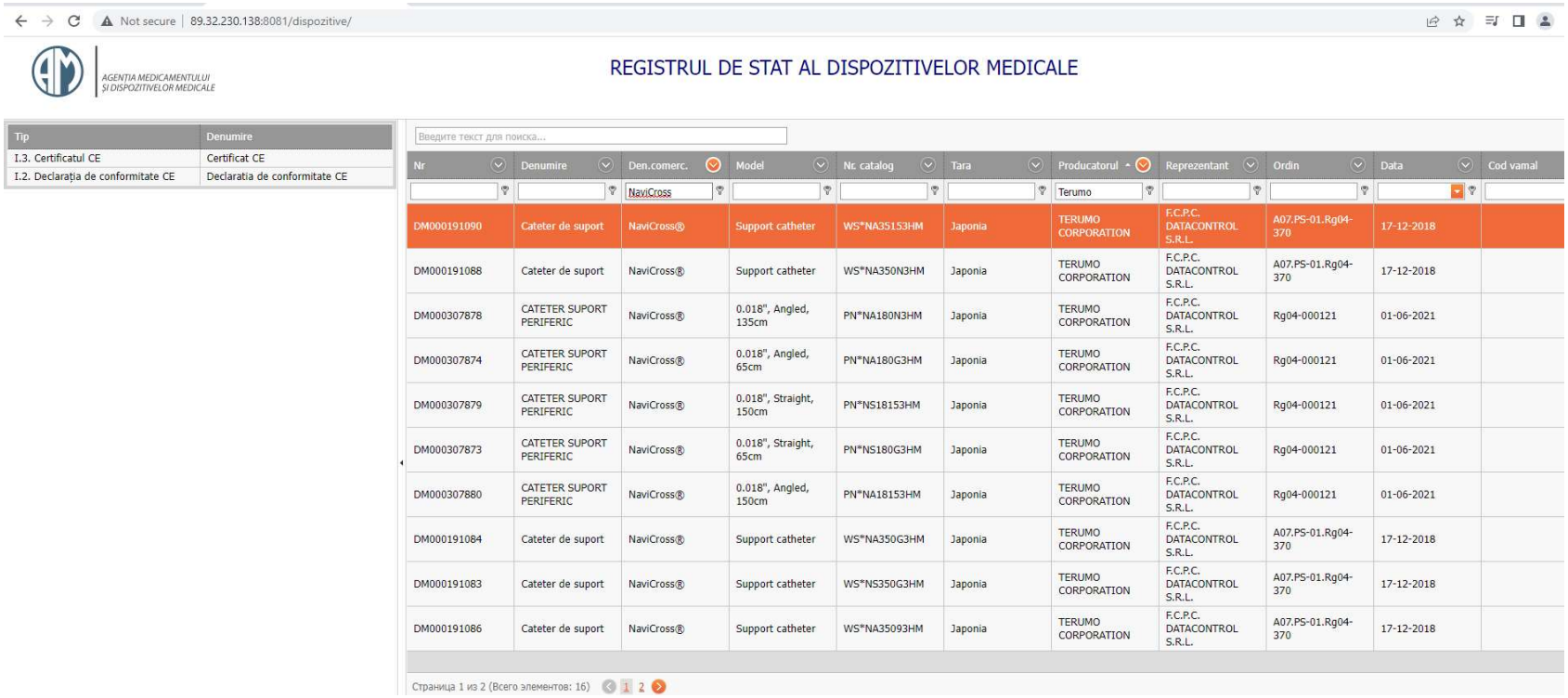

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Date: 2023.02.02 16:30:06 EET
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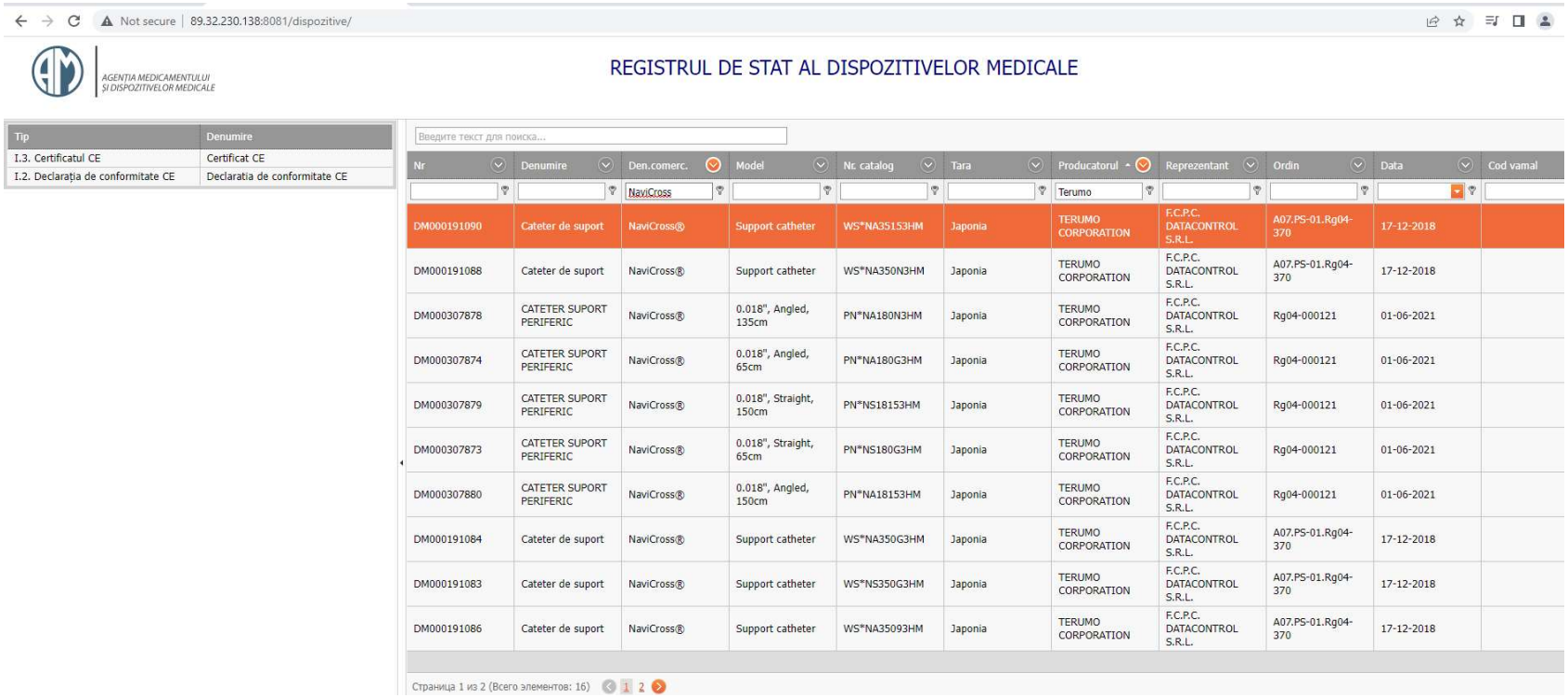
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I.3. Certificatul CE
Certificat CE
I.2. Declarația de conformitate CE
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NaviCross
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DM000191090 Cateter de suport NaviCross® Support catheter WS*NA35153HM Japonia TERUMO CORPORATION F.C.P.C. DATACONTROL S.R.L. A07.PS-01.Rg04-370 17-12-2018
DM000191088 Cateter de suport NaviCross® Support catheter WS*NA350N3HM Japonia TERUMO CORPORATION F.C.P.C. DATACONTROL S.R.L. A07.PS-01.Rg04-370 17-12-2018
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DM000307874 CATETER SUPORT PERIFERIC NaviCross® 0.018", Angled, 65cm PN*NA180G3HM Japonia TERUMO CORPORATION F.C.P.C. DATACONTROL S.R.L. Rg04-000121 01-06-2021
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DM000191084 Cateter de suport NaviCross® Support catheter WS*NA350G3HM Japonia TERUMO CORPORATION F.C.P.C. DATACONTROL S.R.L. A07.PS-01.Rg04-370 17-12-2018
DM000191083 Cateter de suport NaviCross® Support catheter WS*NS350G3HM Japonia TERUMO CORPORATION F.C.P.C. DATACONTROL S.R.L. A07.PS-01.Rg04-370 17-12-2018
DM000191086 Cateter de suport NaviCross® Support catheter WS*NA35093HM Japonia TERUMO CORPORATION F.C.P.C. DATACONTROL S.R.L. A07.PS-01.Rg04-370 17-12-2018
Страница 1 из 2 (Всего элементов: 16) 1 2

Navicross®

Support Catheter

Your first choice in peripheral support catheters
Navicross® is a support catheter for peripheral indications, accepting guidewire diameters up to 0.035" / 0.89 mm.

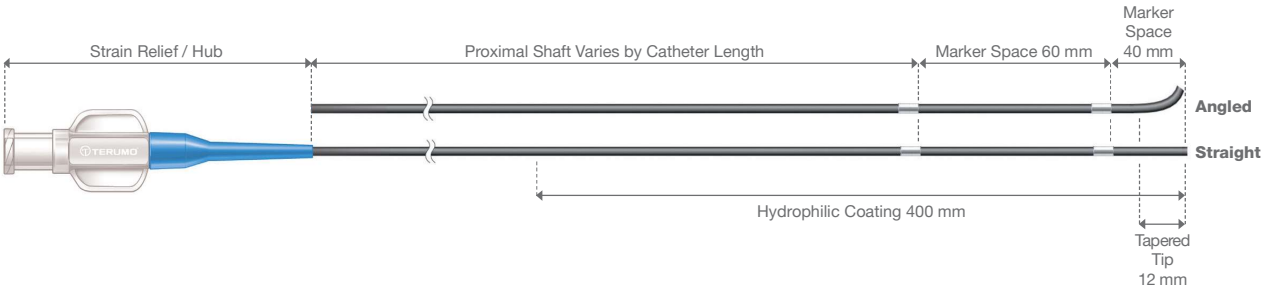
Navicross® is intended to guide and support a guidewire during access of the vasculature except within the cerebral vasculature and the coronary arteries to allow wire exchanges and provide a conduit for the delivery of physiological heparinized saline solution or radiopaque media.

Product Characteristics

Stainless Steel Double Braided Shaft:
- *Provides excellent steerability and efficient push transition in complex lesions;*
- *Enhances torqueability and prevents kinking.*

Minimal Crossing Profile and Tapered Tip:
- *Guarantees a seamless transition between guidewire and catheter facilitating successful lesion access and crossing;*
- *Angulated tip can be used for selecting the true lumen and navigating through bifurcated vessels.*

Unique Three Radiopaque Shaft-Markers:
- *Feasibility of accurate intraluminal measurement (e.g. assessment of treatment dimensions/positions of balloons and stents), because embedded shaft markers are positioned 1 mm from distal tip - 40 mm and 60 mm from precedent marker band.*



General Specifications

Shaft	Stainless steel, Double braided
Catheter length	65, 90, 135 and 150 cm
Wire compatibility	0.035" / 0.89 mm
Markers	1 embedded and 2 swaged radiopaque markers
Tip configuration	Straight and 30° angled
Sheath compatibility	4 Fr (1.39 mm)

Item Specifications

0.035" / 0.89 mm Wire Compatibility	**65 cm**	**90 cm**	**135 cm**	**150 cm**
Straight Tip	WS*NS350G3HM	WS*NS35093HM	WS*NS350N3HM	WS*NS35153HM
30° Angled Tip	WS*NA350G3HM	WS*NA35093HM	WS*NA350N3HM	WS*NA35153HM

Please quote above item reference codes when placing an order

IS616/51GB0616IT1

TERUMO

No.DOC-DQ010-0818/DOC-DQ010-0875

Rev.04

DECLARATION OF CONFORMITY

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

being the manufacturer of:

Navicross

Support Catheter

Product : Catheter, Intravascular, Guiding

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 and B

Tokyo, February 10, 2020
(place and date of issue)

Toshio Nakashima
General Manager
Quality Assurance Department
TERUMO CORPORATION

Digitally signed by Grabazei Alexandru
Date: 2020.04.09 15:35:14 EEST
Reason: MoldSign Signature
Location: Moldova

TERUMO

Appendix A - List of Code Number Structure

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

Character number	Characters	Meanings
1-2	Product	**WS**: Terumo Support catheter
3	Destination	* : for export
4	Classification	**N** : OTW (Over the Wire)
5	Tip shape	**A**: Angle30° **S**: Straight
6-7	Guidewire compatibility	**35**: 0.035inch
8-9	Effective catheter length	**0G**: 65cm, **09**: 90cm, **0N**: 135cm, **15**: 150cm
10	Number of Radiopaque markers	**3**
11	Hydrophilic coating on the distal portion	**H** : 400mm
12	Language for labeling	**M**: Multi-language M26

TERUMO

Appendix B - List of Code Number Structure

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

Character number	Characters	Meanings
1-2	Product	**PN**: Support Catheter for peripheral vasculature
3	Destination	* : for export
4	Classification	**N** : OTW (Over the Wire)
5	Tip shape	**A**: Angle30° **S**: Straight
6-7	Guidewire compatibility	**18**: 0.018inch
8-9	Effective catheter length	**0G**: 65cm, **09**: 90cm, **0N**: 135cm, **15**: 150cm
10	Number of Radiopaque markers	**3**
11	Hydrophilic coating on the distal portion	**H** : 400mm
12	Language for labeling	**M**: Multi-language M27

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

M.Aihara

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.

Digitally signed by Grabazei Alexandru
Date: 2020.04.09 15:35:15 EEST
Reason: MoldSign Signature
Location: Moldova

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60145252 0001
Report No.: 12031336 018

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

Products included:

- Blood Bags
- Blood Donor Set
- Blood Transfusion Filter
- Intravenous Catheter
- Intravenous Administration Set
- Hypodermic Syringe
- Winged Needle
- Dental Needle
- Other Medical Needle
- Blood Administration Set
- Lancet

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Notified Body

Date: 2019-12-23

M.Sc. M. Aihara

TÜVRheinland®

Doc. 2/2, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60145252 0001
Report No.: 12031336 018

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

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Date: 2019-12-23

M.Aihara

M.Sc. M. Aihara

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1485480-1

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

Scope:
Design and Development, Manufacture, Distribution and Service of
- Angiographic Catheter and Accessories
- Anti-adhesion System
- Balloon Dilatation Catheter
- Blood Collection/Transfusion Device and Accessories
- Blood Glucose Monitoring system
- Cartridge Injection System
- Catheter Introducer and Accessories
- Electronic Sphygmomanometer
- Electronic Thermometer
- Embolization Prosthesis and Accessories
- Endoscopic Vessel Harvesting System
- Extracorporeal Circulation Device and Accessories
- Falloposcopic Tuboplasty Device and Accessories
- Guide Wire and Accessories
- Guiding/Micro Catheter and Accessories
- Infusion Pump
- Infusion Set and Accessories

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 150241635-301
Effective date: 2021-08-30
Expiry date: 2023-08-29
Issue date: 2021-08-29

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1485480-1

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

- Intravascular Imaging Catheter and Accessories
- Intravascular Imaging System and Accessories
- Intravenous Catheter
- Left-Ventricular Assist System
- Needle
- Open-heart surgery devices and Accessories
- Oral Care Device and Accessories
- Peritoneal Dialysis Device and Accessories
- Pneumatically-powered Massager
- Prefillable Syringe
- Pulse Oximeter
- Radial Artery Hemostasis Device and Accessories
- Stent System
- Syringe
- Syringe Infusion Pump
- Syringe with Needle
- Thrombus Removal Device
- Tube Catheter and Accessories
- Urine test strip
- Vascular Closure Device
- Vascular Inspection/Treatment Kit
- Vascular prosthesis and Accessories
- Wearable Infusion Pump

Report No.: 150241635-301
Effective date: 2021-08-30
Expiry date: 2023-08-29
Issue date: 2021-08-29

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1485480-1

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

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Terumo Corporation 44-1, 2-chome, Hatagaya Shibuya-ku, Tokyo 151-0072 Japan	Aspects related to Design and Development, Manufacture, Distribution and Service.
/02	c/o Terumo Corporation - Tokyo office 3-20-2, Nishi-Shinjuku Shinjuku-ku, Tokyo 163-1450 Japan	Aspects related to Design and Development and activities related to corporate management processes.
/03	c/o Terumo Corporation, Shonan Center 1500, Inokuchi, Nakai-machi Ashigarakami-gun, Kanagawa 259-0151 Japan	Aspects related to Distribution and activities related to customer communication processes.

Report No.: 150241635-301
Effective date: 2021-08-30
Expiry date: 2023-08-29
Issue date: 2021-08-29

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02