Terumo Medical Corporation
Corporate Headquarters
265 Davidson Avenue, Suite 320
Somerset, New Jersey 08873

January 21, 2022

To whom it may concern

RE: Notification of CE mark status for Angio-Seal™ and FemoSeal™

Dear Valued Customer,

The Angio-Seal and/or FemoSeal vascular closure devices (collectively, the "VCD Products") that your Institution currently purchases from Datacontrol bear a CE mark for compliance with the Medical Device Directive 93/42/EEC ("MDD") that was issued to Terumo Medical Corporation ("TMC"), the legal manufacturer, by British Standards Institute ("BSI") of Netherlands.

Unfortunately, TMC will experience a short-term lapse in the VCD Product's CE Mark as we navigate the remaining process steps to achieve Medical Device Regulation (EU) 2017/745 ("EU MDR") CE mark certification from the National Standards Authority of Ireland ("NSAI"). The Technical Documents required for EU MDR CE mark certification for the VCD Products are currently under active review by NSAI.

To ensure that your Institution continues to receive VCD Products during TMC's EU MDR CE mark certification process, you will continue to receive CE marked VCD Products that were manufactured and placed on the EU market prior to the expiry of the current CE mark certificate.

Please be assured that patient safety and health are our number one priority. We greatly appreciate your support as we navigate this transition from the MDD to the EU MDR with these industry established VCD Products.

Digitally signed by Grabazei Alexandru
Date: 2022.10.08 21:08:17 EEST
Reason: MoldSign Signature
Location: Moldova

If you have any questions, please contact Terumo Medical Corporation, Terumo Europe N.V., or Datacontrol.

Sincerely,

John D. Boselli
Sr. Vice President, Quality Management & Regulatory Affairs
Terumo Medical Corporation

Fien Aerts
Vice President, Regulatory & Vigilance
Authorized Representative
Terumo Europe N.V.

June 2022

Re: Terumo Medical Corporation Derogation for FemoSeal and Angio-Seal

Dear Competent Authority

NSAI is aware that in conjunction with Terumo Medical Corporation's (TMC) Article 59 derogation extension efforts that the Competent Authorities are enquiring when the Notified Body estimates conclusion of conformity assessment activities and issuance of EU MDR certificates.

In response, NSAI has taken steps to resolve reviewer resource constraints and additional reviewers have been onboarded and trained.

TMC has worked with NSAI to resolve remaining queries in a systematic, deliberate and collaborative fashion. At this point, TMC is working to reply to recently provided Round III clinical queries for FemoSeal and are awaiting Round III clinical queries from NSAI for Angioseal. TMC has provided NSAI with expected response dates allowing NSAI to schedule reviewer availability to avoid unnecessary delays. All other sections of the review of technical documentation have been completed or are nearing completion.

Given this, and barring any unforeseen/unexpected challenge, within the next 6 months NSAI aims to be a position to declare a decision on the certification status of this file.

This is based on the assumption that the client can demonstrate sufficient clinical evidence and NSAI can finalise the external clinical expert and expert panel within this time frame.

Lisa Donlon
European Medical Device
Operations Manager
Medical Devices
NSAI

Dr Majella Geraghty
European Medical Device
Operations Manager
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NSAI

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EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. **CE 664636**

Issued To: **Terumo Medical Corporation**
265 Davidson Avenue, Suite 320
Somerset
New Jersey
08873
USA

In respect of:

Angio-Seal Vascular Closure Devices

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC Annex II Section 4 and Regulation 722/2012. The design conforms to the requirements of this directive and regulation. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2017-01-20** Date: **2019-07-18** Expiry Date: **2022-01-19**

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EC Design-Examination Certificate

Supplementary Information to CE 664636

Issued To:

Terumo Medical Corporation
265 Davidson Avenue, Suite 320
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USA

Angio-Seal Vascular Closure Device

Model Number	Description
610120	6F Angio-Seal STS-Plus
610122	8F Angio-Seal STS-Plus
610132	6F Angio-Seal VIP
610133	8F Angio-Seal VIP
C610136	6F Angio-Seal Evolution
C610137	8F Angio-Seal Evolution

First Issued: **2017-01-20** Date: **2019-07-18** Expiry Date: **2022-01-19**

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EC Design-Examination Certificate

Supplementary Information to CE 664636

Issued To:

Terumo Medical Corporation
265 Davidson Avenue, Suite 320
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New Jersey
08873
USA

Certificate History

Date	Reference Number	Action
20 January 2017	10167452	First Issue.
27 February 2019	8798156	Traceable to NB 0086.
Current	9659425	Change in legal manufacturer address.

First Issued: **2017-01-20** Date: **2019-07-18** Expiry Date: **2022-01-19**

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Terumo Europe NV

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www.terumo-europe.com

To whom it may concerns,

Dear valued customer,

Terumo Medical Corporation (TMC) is the legal manufacturer of Angio-Seal™ vascular closure devices. This product has been on the market in Europe and elsewhere for many years and were initially CE Marked in 1999 and has maintained the CE Mark ever since.
An MDR application was submitted to notified body, NSAI, in November 2020. Since then, despite three rounds of technical and clinical review which have already occurred, TMC still works with NSAI to complete the review with the objectives to obtain the MDR recertification in due time.

The length of the overall process has posed a risk of MDD certificate expiry since January 19th prior to the issuance of the MDR certificate. In this case, TMC has requested a temporary derogation under Article 59 and permission to continue to market Angio-Seal™ until we receive an MDR CE Mark certification from NSAI.
TMC has obtained derogation approvals from 21 of the Member States in addition to United Kingdom, Switzerland, Iceland and Norway. Please see **Attachment 1** for a listing of all **derogation approvals**.

Quantities of Angio-Seal™ with MDD CE mark which arrived in Europe before 19th of January have been available in most of the markets until the end of June.

During the period of MDR CE recertification, Terumo can temporarily offer AngioSeal™ products without CE Mark on product label.

TMC greatly appreciates your consideration of this request and please let us know if you require any further documentation to support your decision.

Kind regards,

Louise LEE
Group marketing Manager, EMEA
Terumo Europe

ATTACHMENT 1

Competent Authority	Country
BASG	Austria
afmps	Belgium
BDA	Bulgaria
HALMED	Croatia (Hrvatska)
MPHS	Cyprus
SUKL	Czech Republic
DKMA	Denmark
TERVISEAMET	Estonia
Valvira	Finland
ANSM	France
BfArM	Germany
EOF	Greece
HRTC	Hungary
HPRA	Ireland
ZVA	Latvia
VASPVT	Lithuania
MS	Luxembourg
Medicines Authority	Malta
IGZ	Netherlands
NMA	Norway
URPL	Poland
INFARMED	Portugal
ANM	Romania
SUKL	Slovakia
JAZMP	Slovenia
AEMPS	Spain
MPA	Sweden
SwissMedic	Switzerland
MHRA	United Kingdom

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Terumo Medical Corporation
265 Davidson Avenue, Suite 320
Somerset
New Jersey
08873
USA

DUNS Number: 96-252-0628

Holds Certificate No: **MDSAP 695791**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design and Development, Manufacture and Distribution of Sterile Vascular Closure Devices

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-03-03 Effective Date: 2020-03-03 Expiry Date: 2023-03-02

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP authorized auditing organization

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 664635**

Issued To: **Terumo Medical Corporation**
265 Davidson Avenue, Suite 320
Somerset
New Jersey
08873
USA

In respect of:

Design, development and manufacture of sterile vascular closure devices

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2017-01-20** Date: **2019-07-18** Expiry Date: **2022-01-19**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 664635**
Date:	**2019-07-18**
Issued To:	**Terumo Medical Corporation** **265 Davidson Avenue, Suite 320** **Somerset** **New Jersey** **08873** **USA**

Subcontractor:	**Service(s) supplied**
DSM Biomedical 735 Pennsylvania Drive Exton PA 19341 USA	**Animal Tissues / Derivatives**
St. Jude Medical 14901 DeVeau Place Minnetonka Minnesota 55345-2126 USA	**Manufacture**
St. Jude Medical Costa Rica Ltda. Edificio #44, Calle 0, Ave. 2 Zona Franca El Coyol, Alajuela Costa Rica	**Manufacture**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 664635**
Date:	**2019-07-18**
Issued To:	**Terumo Medical Corporation** **265 Davidson Avenue, Suite 320** **Somerset** **New Jersey** **08873** **USA**

Subcontractor:	**Service(s) supplied**
Sterigenics US, LLC 1700 College Boulevard West Memphis AR 72301 USA	**Gamma Sterilization**
Sterigenics US, LLC 1003 Lakeside Drive Gurnee Illinois 60031 USA	**Gamma Sterilization**
Synergy Health AST SRL B13.1 Street 4, Avenue 1 El Coyol Free Zone 20102 El Coyol Alajuela Costa Rica	**ETO Sterilization**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 664635**
Date:	**2019-07-18**
Issued To:	**Terumo Medical Corporation** **265 Davidson Avenue, Suite 320** **Somerset** **New Jersey** **08873** **USA**

Subcontractor:	**Service(s) supplied**
Terumo Europe, N.V. Interleuvenlann 40, B-3001 Leuven Belgium	**EU Representative**
Terumo Puerto Rico LLC Innovation Street Lot 21 Caguas West Industrial Park Caguas 00725 Puerto Rico	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 664635**

Date: **2019-07-18**

Issued To: **Terumo Medical Corporation**
265 Davidson Avenue, Suite 320
Somerset
New Jersey
08873
USA

Date	Reference Number	Action
20 January 2017	8645594	First issue.
20 October 2017	8794520	Update name and address of subcontractor Terumo Puerto Rico LLC.
27 February 2019	8798156	Traceable to NB 0086.
Current	9659326	Change in legal manufacturer address Updated address of Terumo Puerto Rico LLC to align with BSI ISO certificates.

PUSHING BOUNDARIES

Terumo Interventional Systems **broadens your reach** with new tools and techniques in interventional medicine.

We're relentlessly seeking new ways to help you apply effective solutions and achieve **better outcomes for more patients**.

TERUMO INTERVENTIONAL SYSTEMS

Angio-Seal®
Vascular Closure Device

ORDERING INFORMATION

ANGIO-SEAL VIP		
PRODUCT CODE	FRENCH SIZE	GUIDEWIRE DIAMETER (in)
610130	6	0.035
610131	8	0.038
ANGIO-SEAL EVOLUTION™		
PRODUCT CODE	FRENCH SIZE	GUIDEWIRE DIAMETER (in)
C610134	6	0.035
C610135	8	0.038
ANGIO-SEAL STS PLUS		
PRODUCT CODE	FRENCH SIZE	GUIDEWIRE DIAMETER (in)
610119	6	0.035
610121	8	0.038

Contents: Vascular Closure Device, Insertion Sheath, Arteriotomy Locator and 70 cm Guidewire with "J" Straightener (10 units per box).

FIND OUT MORE Phone: 800.862.4143 terumois.com Fax: 800.411.5870

Indications
The Angio-Seal Vascular Closure Device product family, including the STS Plus, VIP and Evolution platforms, is indicated for use in closing and reducing time to hemostasis of the femoral arterial puncture site in patients who have undergone diagnostic angiography procedures or interventional procedures using an 8 French or smaller procedural sheath for the 8 F Angio-Seal device and a 6 French or smaller procedural sheath for the 6 F Angio-Seal device. The Angio-Seal STS Plus, VIP and Evolution platform devices are also indicated for use to allow patients who have undergone diagnostic angiography to safely ambulate as soon as possible after sheath removal and device placement, as well as to allow patients who have undergone an interventional procedure to safely ambulate after sheath removal and device placement.

Important Safety Information
Possible adverse events for vascular closure devices include, but are not limited to: bleeding or hematoma, AV fistula or pseudoaneurysm, infection, allergic reaction, foreign body reaction, inflammation or edema. This device should only be used by a licensed physician (or other health care professional authorized by or under the direction of such physician) possessing adequate instruction in the use of the device, e.g., participation in an Angio-Seal physician instruction program or equivalent.

RX ONLY. Refer to the product labels and package insert for complete warnings, precautions, potential complications, and instructions for use.

References:

1. Kussmaul WG 3rd, Buchbinder M, Whitlow PL, et al. Rapid arterial hemostasis and decreased access site complications after cardiac catheterization and angioplasty: results of a randomized trial of a novel hemostatic device. *J Am Col Cardiol.* 1995;25(7):1685-92.
2. Nash JE, Evans DG. The Angio-Seal™ hemostatic puncture closure device. Concepts and experimental results. *Herz.* 1999;24(8):597-606.
3. Applegate RJ, Turi Z, Sachdev N, et al. The Angio-Seal Evolution Registry: outcomes of a novel automated Angio-Seal vascular closure device. *J Invasive Cardiol.* 2010;22(9):420-6.
4. Data on file.
5. Tellez A, Cheng Y, Yi GH, et al. *In vivo* intravascular ultrasound analysis of the absorption rate of the Angio-Seal™ vascular closure device in the porcine femoral artery. *EuroIntervention.* 2010;5(6):731-6.
6. Aker UT, Kensey KR, Heuser RR, Sandza JG, Kussmaul WG 3rd. Immediate arterial hemostasis after cardiac catheterization: initial experience with a new puncture closure device. *Catheter Cardiovasc Diagn.* 1994;31(3):228-32.
7. Applegate RJ, Rankin KM, Little WC, Kahl FR, Kutcher MA. Restick following initial Angioseal use. *Catheter Cardiovasc Interv.* 2003;58(2):181-184.

TERUMO INTERVENTIONAL SYSTEMS

Angio-Seal®
Vascular Closure Device

THE INSIDE ADVANTAGE™

Bioabsorbable + Dual Security

TERUMO INTERVENTIONAL SYSTEMS

Angio-Seal®
Vascular Closure Device

HELP ENSURE **SUCCESSFUL HEMOSTASIS**

The ANGIO-SEAL active closure anchor gives you the inside advantage. The anchor creates a mechanical seal from the inside out—here's how:

- **The anchor supports proper location for a reliable seal and collagen positioning[1,2]:**

  99.7% deployment success[3]

  97.8% hemostasis by device[3]

- **The anchor and seal are bioabsorbed:**
  - Fibrin coats the anchor within hours and becomes totally encapsulated in 7-14 days[4]
  - Anchor begins to hydrate and soften 24-36 hours after deployment[4]
  - Anchor is absorbed 95% at 42 days[5]
  - All components are absorbed within 60-90 days[1, 2, 6, 7]

- **Arterial flow is not compromised, no evidence of chronic scar tissue or inflammation[5,6]**

ANGIO-SEAL® STS Plus

RELY ON **DUAL SECURITY**

The bioabsorbable ANGIO-SEAL anchor + collagen provides dual security, ensuring it is positioned correctly and stays in place[1,2]

- **Bioabsorbable Anchor**
  Designed to fit closely against the arterial wall, leaving blood flow undisturbed with no residual stenosis[5]

- **Bioabsorbable Collagen**
  Designed to conform to the arteriotomy for confident closure[2]

- **Bioabsorbable Suture**
  Tethers the anchor and collagen together, providing a secure seal[2]

ANGIO-SEAL® VIP

ANGIO-SEAL® Evolution™

PERFORM RESTICK WITH CONFIDENCE

Clinical data supports the safety of restick following an initial ANGIO-SEAL deployment[7]

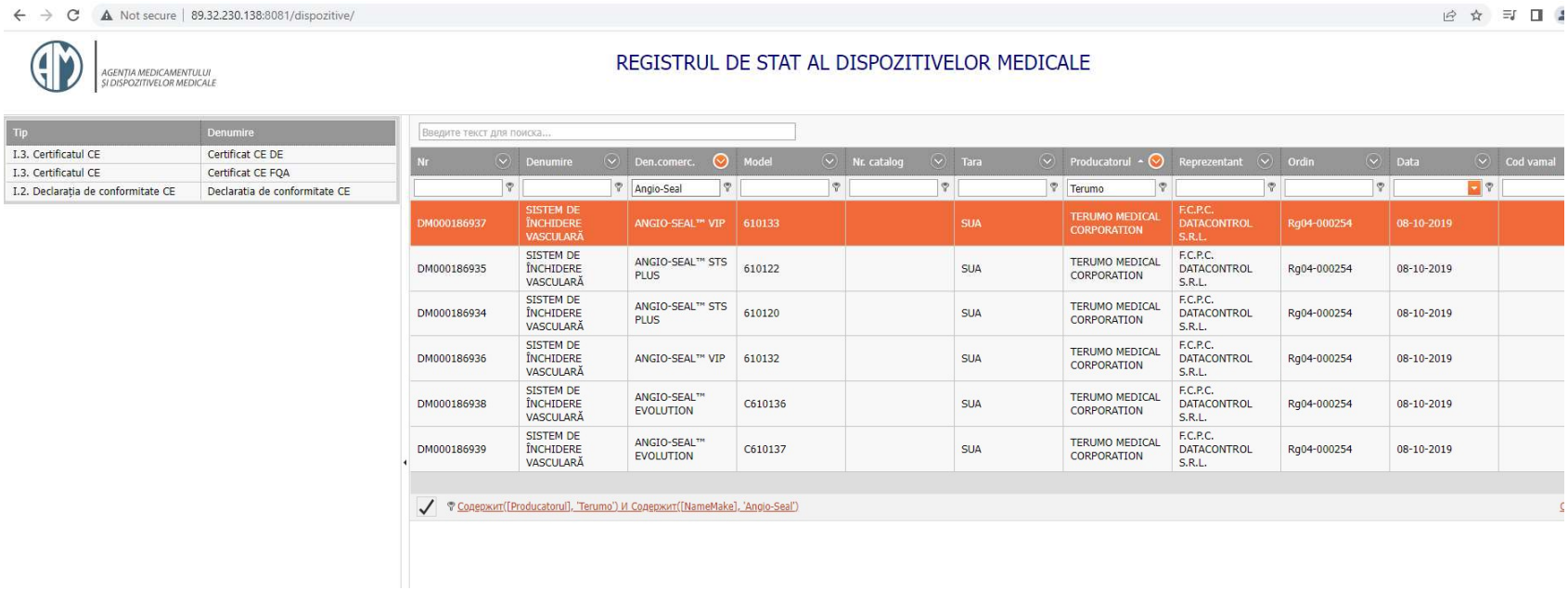
- Restick can be performed without device dislodgement or any significant vascular complications
- Arterial closure can be achieved with a second ANGIO-SEAL Vascular Closure Device

Vascular Complications Following Restick

COMPLICATIONS		PROPORTION	95% CONFIDENCE INTERVAL
Large Hematoma (≥ 10cm)	3	0.0166	0.0043 – 0.0515
Vessel Occlusion	0	0	0 – 0.0259
Pseudoaneurysm	0	0	0 – 0.0259
AV Fistulae	0	0	0 – 0.0259
Major Bleeding	0	0	0 – 0.0259
Vascular Repair	0	0	0 – 0.0259
Death	0	0	0 – 0.0259

A clinical study of 181 patients evaluated safety and efficacy of a restick of the same artery following an initial ANGIO-SEAL device deployment. Patients were included in the study if they had an ANGIO-SEAL device deployment and subsequently underwent arterial access using the same artery that had previously been closed with an ANGIO-SEAL device within 90 days of the original device placement.

TERUMO
INTERVENTIONAL SYSTEMS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SISTEM DE ÎNCHIDERE VASCULARĂ
ANGIO-SEAL™ VIP
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TERUMO MEDICAL CORPORATION
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SISTEM DE ÎNCHIDERE VASCULARĂ
ANGIO-SEAL™ STS PLUS
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SISTEM DE ÎNCHIDERE VASCULARĂ
ANGIO-SEAL™ STS PLUS
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TERUMO MEDICAL CORPORATION
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Rg04-000254
08-10-2019
DM000186936
SISTEM DE ÎNCHIDERE VASCULARĂ
ANGIO-SEAL™ VIP
610132
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TERUMO MEDICAL CORPORATION
F.C.P.C. DATACONTROL S.R.L.
Rg04-000254
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SISTEM DE ÎNCHIDERE VASCULARĂ
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SISTEM DE ÎNCHIDERE VASCULARĂ
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C610137
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TERUMO MEDICAL CORPORATION
F.C.P.C. DATACONTROL S.R.L.
Rg04-000254
08-10-2019
Содержит([Producatorul], 'Terumo') И Содержит([NameMake], 'Angio-Seal')