

ORDIN DE PLATA NR.: 26

TIP.DOC. 1

DATA EMITERII:19 martie 2021

PLATITI: 1200-00

LEI: Una Mie Doua Sute lei 00 bani

PLATITOR: (R) S.C. "OXIVI
T-MED" S.R.L.

CONTUL DE PLATI/CODUL IBAN
MD44ML000000002251729503
CODUL FISCAL :1007600044280 /

PRESTATORUL PLATITOR

CODUL BANCII:

BC"Moldindconbank"S.A. fil."Invest" Chisinau

:MOLDMD2X329:

BENEFICIAR (R)IMSP Spitalu
l Clinic Republican "Timofei
Mosnea

CONTUL DE PLATI/CODUL IBAN
MD32ML000000002251502448
CODUL FISCAL :1003600150783 /

PRESTATORUL BENEFICIAR

CODUL BANCII:

BC"Moldindconbank"S.A.

:MOLDMD2X

DESTINATIA PLATII:Pentru garantia pentru:
oferta la procedura de achizi?ie public:
a nr ocds-b3wdp1-MD-1614254010289 din 9:
mart 2021, 9:00 - 19 mart 2021, 15:00

TIPUL TRANSFERULUI
NORMAL/URGENT :N:

L.S.

CODUL TRANZACTIEI:001:

DATA PRIMIRII:19/03/2021

DATA EXECUTARII:

SEMNETURILE

EMITENTULUI

CONDUCATOR:Web Kojevnikov Dmitrii

MIIGfAYJKoZIhvcNAQcCoIIGbTCCBmkCAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB3:
DQEHAaCCBIUwggSBMIIDaaADAgECAhNHAACEjCA/4xcrKCbfAAAAAISMMa0GCSqG:
SIB3DQEBcWUAMCIXIDAeBgNVBAMTF0NFU1QxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIwMDMxNjA4NDUwM1oXDTIzMDMxNjA4NTUwM1owgbGxCzAJBgNVBAYTAk1EMRow:
YDVQIExFSZXB1YmXpY2EgTW9sZG92YTERMA8GA1UEBxMIQ2hpc2luYXUxZzAV

(semnatura electronica)

CONTABIL-SEF:Web Kojevnikov Dmitrii

MIIGfAYJKoZIhvcNAQcCoIIGbTCCBmkCAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB3:
DQEHAaCCBIUwggSBMIIDaaADAgECAhNHAACEjCA/4xcrKCbfAAAAAISMMa0GCSqG:
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DTIwMDMxNjA4NDUwM1oXDTIzMDMxNjA4NTUwM1owgbGxCzAJBgNVBAYTAk1EMRow:
YDVQIExFSZXB1YmXpY2EgTW9sZG92YTERMA8GA1UEBxMIQ2hpc2luYXUxZzAV

L.S.

(semnatura electronica)

CONDUCATOR:

(semnatura manuala)

CONTABIL-SEF:

(semnatura manuala)

SEMNETURA PRESTATORUL

L.S.

MOTIVUL REFUZULUI

L.S.

REPUBLICA



MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

Societatea Comercială "OXIVIT-MED" S.R.L.

ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de identificare de stat - codul fiscal
1007600044280

Data înregistrării

30.07.2007

Data eliberării

30.07.2007

Bordeianu Tatiana, registrator de stat

*Funcția, numele, prenumele persoanei
care a eliberat certificatul*

semnătura

MD 0067985





REPUBLICA MOLDOVA
LICENȚĂ

Seria A MMII

Nr. 044647

Denumirea autorității de licențiere

Camera de Licențiere

Denumirea, forma juridică de organizare, sediul
(adresa juridică) a titularului de licență

**Societatea Comercială „OXIVIT-
MED” S.R.L.**

mun. Chișinău, bd. Decebal, 82, ap. 90

Data și numărul certificatului de
înregistrare de stat a titularului de licență

30.07.2007 MD 0067985

Numărul de înregistrare
a întreprinderii sau IDNO

1007600044280

Codul fiscal

Genul de activitate, integral sau parțial,
pentru a cărui desfășurare se eliberează licența

*** Importul și comercializarea dispozitivelor
medicale ***

Data eliberării licenței

15 octombrie 2012

Valabilă până la
Prelungită până la: 15.10.2022

15 octombrie 2017

**Semnătura conducătorului
autorității de licențiere**

Director al Camerei de Licențiere

Valentin GUZNAC

Notă: Licența este valabilă numai cu anexa autenticată de autoritatea de licențiere,
în care sînt indicate condițiile de licențiere pentru genul de activitate specificat în licență.

Nr. 12101-30418.03.2016

CERTIFICAT PRIVIND EXISTENTA CONTURILOR CURENTE

Prin prezentul, **BC „Mobiasbancă – Groupe Societe Generale” S.A.**, codul băncii (BIC): **MOBBMD22**, confirmă că compania **OXIVIT-MED SRL**, cod fiscal (IDNO) **1007600044280**, deține următoarele conturi curente la BC "Mobiasbancă-Groupe Societe Generale" S.A., Filiala. 1 Stejaur :

1. **MDL - 2224710SV23488147100; IBAN- MD09MO2224ASV23488147100**
2. **EUR - 2224710SV22227957100; IBAN- MD17MO2224ASV22227957100**
3. **USD - 2224710SV22214937100; IBAN- MD86MO2224ASV22214937100**

Certificatul este emis în baza cererii întreprinderii: Oxivit-Med SRL.


Dumitru Popa
Director filială „Stejaur”



Executor : Mariana Guzun
Tel: 022 812 614

Filiala Nr. 1 „Stejaur”
Bd. Ștefan cel Mare și Sfânt 196
MD-2004, Chișinău, Moldova
Cod MOBBMD22
Cont de corespondență 35213892
la Centrul de Decontări al BNM

Tel. +373 22 81 26 15
Fax. +373 22 81 26 15
www.mobiasbanca.md

BC „Mobiasbancă – Groupe Société Générale” SA
Capital Social: 100 000 000 MDL
Număr de înregistrare de stat - 1002600006089
Sediul Central:
bd. Ștefan cel Mare și Sfânt 81a
MD-2012, Chișinău, Moldova



„CAMERA ÎNREGISTRĂRII DE STAT” Î.S.
Secția fonduri speciale și informații curente

EXTRAS
din Registrul de stat al persoanelor juridice

nr. 71 din 05.01.2016

Denumirea completă: **Societatea Comercială «OXIVIT-MED» S.R.L.**

Denumirea prescurtată: **S.C. «OXIVIT-MED» S.R.L.**

Forma juridică de organizare: **Societate cu Răspundere Limitată.**

Numărul de identificare de stat și codul fiscal: **1007600044280.**

Data înregistrării de stat: **30.07.2007.**

Sediul: **MD-2032, bd. Decebal, 82, ap.(of.) 90, mun. Chișinău, Republica Moldova.**

Modul de constituire: **nou creată.**

Obiectul principal de activitate:

- 1 Importul, fabricarea, comercializarea, asistența tehnică și (sau) reparația dispozitivelor medicale și (sau) a opticii;**
- 2 Comerțul cu ridicata al parfumurilor și produselor cosmetice;**
- 3 Comerțul cu amănuntul al produselor cosmetice și de parfumerie, articolelor de toaletă;**
- 4 Intermedieri pentru vânzarea unui asortiment larg de mărfuri;**
- 5 Alte tipuri de comerț cu amănuntul în magazine nespecializate;**
- 6 Alte tipuri de comerț cu ridicata;**
- 7 Închirierea altor mașini și echipamente.**

Capitalul social: **5400 lei.**

Administrator: KOJEVNIKOV DMITRII, IDNP 0972305012362,

Asociați:

1. KOJEVNIKOV DMITRII , IDNP 0972305012362

cota 5400.00 lei, ce constituie 100 %.

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: 05.01.2016.

Specialist principal
tel. 022-266-252



Lazari Aliona





c/f: 10037600044280; adresa: str. Independenței 28-34, or. Chișinău, Republica Moldova
telefon: + 373 22 808002; fax: + 373 22 808003
web: www.oxivit-med.com; e-mail: info@oxivit-med.com

Lista fondatorilor companiei SRL „Oxivit-Med”

Nr.	Numele, Prenumele	Codul Personal
1	Kojevnikov Dmitrii	09723015012362

CERTIFICATE

Number: 2090418

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands

including the implementation meets the requirements of the standard:

EN ISO 13485:2016
ISO 9001:2015

Scope:

Sales, order management, warehousing and distribution of medical devices.
Including inventory management, regulatory affairs, post market surveillance, technical service, customer education and spine loaner operations

Certificate expiry date: 1 July 2021
Certificate effective date: 1 July 2018
Certified since: 1 July 2006

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed



ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Certified organization(s) and/or locations:

Different scope

Medtronic Portugal LDA-
Rua Tomas da Fonseca Torre E, 11
 piso
1600 Lisboa
Portugal

Sales, Order Management and distribution of medical devices
including technical service and customer education.

Warehousing and distribution of medical devices, including spine
loaner operations

Medtronic Italia S.p.A.
Via Varesina 162
20156 Milano
Italy

Sales, order management and distribution of medical devices.
Including technical service and customer education.
Promotion, invoice and order management of medicinal
products.

Medtronic Danmark A/S.
Arne Jacobsens Allé 17
2300 Copenhagen
Denmark

Sales, order management and distribution of medical devices.
Including technical service and customer education

Medtronic Medikal Teknoloji Ticaret Ltd
Sti
Saray Mah. Esnaf Sk.
Akkom Ofis Park Laodik Plaza
Sitesi B Blok Apt: 2/8
00000 Umraniye - Istanbul
Turkey

Sales, order management and distribution of medical devices.
Including technical service and customer education

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Africa (Pty) Ltd.
Waterfall Distribution Campus
CNR K101 and Bridal Veil Road
Waterfall Midrand
1685 Gauteng
South Africa

Sales, order management, warehousing and distribution of medical devices. Including technical service, customer education and spine loaner operations.

Medtronic Ibérica S.A.
Calle de María de Portugal, 11
28050 Madrid
Spain

Sales, order management, warehousing and distribution of medical devices. Including technical service, customer education and spine loaner operations.

Medtronic Romania SRL
Ploiesti 42-44, Building B, B2
Wing, 2nd floor, district 1
Baneasa Business & Technology Park
013696 Bucharest
Romania

Sales, order management and distribution of medical devices. Including technical service and customer education.

Medtronic Norge AS
Martin Linges vei 25
1364 Fornebu
Norway

Sales, order management and distribution of medical devices. Including technical service and customer education.

Medtronic Portugal, LDA-
Avenida Gomes Pereira 61B
Benfica
1600 Lisboa
Portugal

Sales, Order Management and distribution of medical devices Including technical service and customer education.

Warehousing and distribution of medical devices, including spine loaner operations.

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Service & Repair CoE
C-Mill gebouw K
Jan Campertstraat 21-A
6416 SG Heerlen

Service and repair of medical devices (excluding Imaging and Navigation products).

Medtronic Ibérica S.A.
Polígono Industrial La Garena
Calle Francisco Rabal 7
28806 Alcalá De Heneras, Madrid
Spain

Spine loaner operations.

Medtronic Ibérica S.A.
WTC Almeda Park
Placa de la Pau, s/n. Edificio 7, 3 piso
08940 Cornellà de Llobregat, Barcelona
Spain

Warehousing and distribution of medical devices, including spine loaner operations

Medtronic France SAS
27/33 Quai Alphonse Le Gallo
92513 Boulogne-Billancourt
France

Sales, order management and distribution of medical devices. Including technical Service and customer education

Medtronic Trading NL B.V.
Larixplein 4
5616 VB Eindhoven

Sales, order management and distribution of medical devices. Including technical service and customer education

Medtronic GmbH
Earl-Bakken-Platz 1
40670 Meerbusch
Germany

Distribution of medical Devices, medical equipment and related services.

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Österreich GmbH
Millennium Tower, 20th floor
Handelskai 94-96
1200 Wien
Austria

Sales, order management, warehousing and distribution of medical devices. Including technical Service and customer education

Medtronic (Schweiz) AG
Talstrasse 9
3053 Munchenbuchsee
Switzerland

Sales, order management, warehousing and distribution of medical devices. Including technical Service and customer education

Medtronic Hellas S.A.
Avenue Kifisias 24 Building B
151 25 Marousi Pref. Attica
Greece

Sales, order management and distribution of medical devices. Including technical service and customer education.

Medtronic Serbia Ltd.
Bulevar Zorana Djindjica, 64a
11070 Belgrade
Serbia

Sales, order management and distribution of medical devices.

Medtronic Hungária Kft.
Bocskai út 134-146
Cépulet 3. emelet
1113 Budapest
Hungary

Sales, order management and distribution of medical devices. Including customer education.

Medtronic CCO SSC Warsaw
Polna 11
00-633 Warszawa
Poland

Order management of medical devices.

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Finland Oy
Lentäjätie 3
01530 Vantaa
Finland

Sales, order management and distribution of medical devices.
Including technical service and customer education.

Medtronic AB
P.O. Box 1034
164 21 Kista
Sweden

Sales, order management and distribution of medical devices.
Including technical service and customer education

Medtronic Trading Ltd.
10 Hamada Street
4673344 Herzlya
Israel

Import, sales, order management and distribution of medical
devices. Including technical service and customer education

Addendum expiry date: 1 July 2021
Addendum effective date: 1 July 2018

AORTIC PERIPHERAL AND VENOUS PRODUCT CATALOGUE

AORTIC

PERIPHERAL

VENOUS



Medtronic
Further, Together

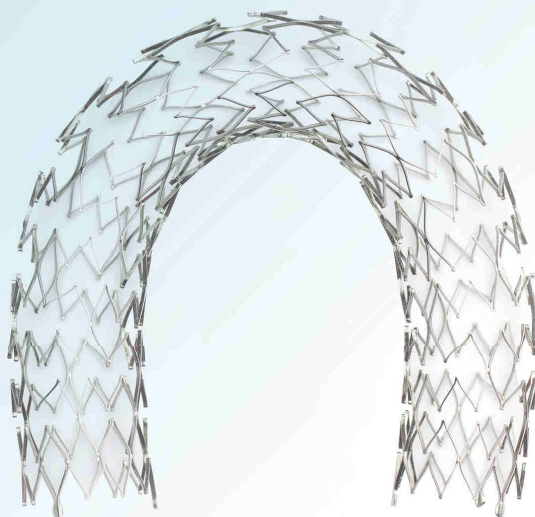
Abre™

Venous Self-expanding Stent System

AORTIC

PERIPHERAL

VENOUS



The stent made for the unique challenges of deep venous disease.

The Abre™ System size difference

- A full range of sizes specifically tailored for the iliofemoral venous profile
- A consistent 9 F delivery system across our full matrix for a simplified procedure
- Catheter length of 90 cm that supports all three primary access sites and can be used with a standard length guidewire

Venous Self-expanding Stent System

ORDER INFORMATION

Product Catalogue Number	Stent Diameter (mm)	Stent Length (mm)	Catheter Length (cm)	Estimated Anatomic Vessel Diameter (mm)
AB9G10040090	10	40	90	7.5-9.5
AB9G10060090	10	60	90	7.5-9.5
AB9G10080090	10	80	90	7.5-9.5
AB9G10100090	10	100	90	7.5-9.5
AB9G10120090	10	120	90	7.5-9.5
AB9G10150090	10	150	90	7.5-9.5
AB9G12060090	12	60	90	9.5-11.5
AB9G12080090	12	80	90	9.5-11.5
AB9G12100090	12	100	90	9.5-11.5
AB9G12120090	12	120	90	9.5-11.5
AB9G12150090	12	150	90	9.5-11.5
AB9G14060090	14	60	90	11.5-13.5
AB9G14080090	14	80	90	11.5-13.5
AB9G14100090	14	100	90	11.5-13.5
AB9G14120090	14	120	90	11.5-13.5
AB9G14150090	14	150	90	11.5-13.5
AB9G16060090	16	60	90	13.5-15.5
AB9G16080090	16	80	90	13.5-15.5
AB9G16100090	16	100	90	13.5-15.5
AB9G16120090	16	120	90	13.5-15.5
AB9G16150090	16	150	90	13.5-15.5
AB9G18060090	18	60	90	15.5-17.5
AB9G18080090	18	80	90	15.5-17.5
AB9G18100090	18	100	90	15.5-17.5
AB9G18120090	18	120	90	15.5-17.5
AB9G18150090	18	150	90	15.5-17.5
AB9G20060090	20	60	90	17.5-19.0
AB9G20080090	20	80	90	17.5-19.0
AB9G20100090	20	100	90	17.5-19.0
AB9G20120090	20	120	90	17.5-19.0
AB9G20150090	20	150	90	17.5-19.0

VACS® II / VACS® III

Interventional and Pediatric Cardiology / Heart Surgery



+++

Perkutaner transluminaler Valvuloplastie (PTV)-Katheter für den Einsatz
in der interventionellen Erwachsenen- und Kinderkardiologie
*Percutaneous Transluminal Valvuloplasty (PTV) Catheter for Pediatric
and Adult Interventional Cardiology*

OSYPKA
Technology for an active life

VACS® II / VACS® III

Perkutaner Transluminaler Valvuloplastie (PTV)-Katheter

Der **VACS®** Dilatationskatheter ist ein PTV-Ballonkatheter mit koaxialem Aufbau und non-compliant Ballon, der über einen Führungsdraht (over-the-wire) exakt platziert werden kann.

Das geringe Ballonprofil des **VACS® II** Ballonkatheters gestattet die Verwendung eines kleinstmöglichen Einführbestecks. Dagegen bietet der **VACS® III** Ballonkatheter durch ein verstärktes Ballonsegment eine außergewöhnlich hohe Druckbelastbarkeit.

Indikationen:

- Aortenklappen-Prädilatation bei TAVI-Prozeduren
- Aortenisthmus-Stenosen
- Ausflusstrakt-Stenosen des rechten und linken Ventrikels
- Pulmonalklappenstenosen
- Aortenklappenstenosen
- Periphere Pulmonalarterienstenosen

Besondere Eigenschaften:

- Atraumatische Spitze
- Kurze Inflations- und Deflationszeiten
- Röntgensichtbare Markierungsringe aus Gold
- Umfassendes Größenspektrum für größtmögliche Flexibilität

Technische Daten für VACS® II / VACS® III:

- Ballondurchmesser 4–30 mm / 5–30 mm
- Ballonlänge 20–60 mm / 20–60 mm
- Maximaldruck 6–1,5 atm / 15–4 atm

Percutaneous Transluminal Valvuloplasty (PTV) Catheter

The **VACS®** dilatation catheter is a PTV Balloon Catheter with a coaxial shaft construction and a non-compliant balloon which can easily be placed over a guide wire. The low balloon profile of the **VACS® II** balloon catheter allows the use of smallest introducers. The **VACS® III** is a particularly high pressure balloon catheter due to a reinforced balloon segment.

Indication:

- Aortic valve pre-dilatation during TAVI procedures
- Stenosis of the aortic isthmus
- Outflow tract stenosis of the right and left ventricle
- Pulmonary valve stenosis
- Aortic valve stenosis
- Peripheral pulmonary artery stenosis

Special Features:

- Atraumatic tip
- Short inflation and deflation duration
- Radiopaque gold markers
- Comprehensive size range for maximal flexibility

Technical Data VACS® II / VACS® III:

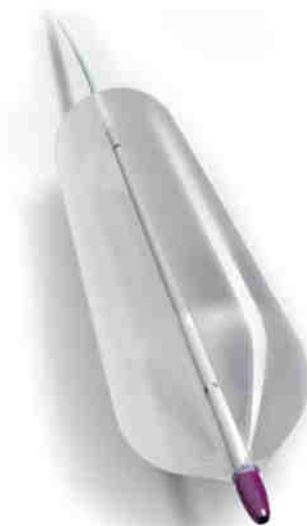
- Balloon diameter 4–30 mm / 5–30 mm
- Balloon length 20–60 mm / 20–60 mm
- Rated Burst Pressure 6–1.5 atm / 15–4 atm

VACS® II

- Dünnes und weiches Ballonmaterial für kleinstmöglichen Gefäßzugang im pädiatrischen Einsatz oder in der Erwachsenenvalvuloplastie
- *Thin and soft balloon material for a minimized vascular access profile in pediatric procedures as well as palliative or bridging valvuloplasty*

VACS® III

- Besonders druck- und beschädigungsrestistenter Ballon für anspruchsvolle Anwendungen ohne besondere Herausforderungen an den Gefäßzugang
- Größerer Katheterschaft für schnelle In- und Deflation
- *Outstanding pressure- and tear-resistant balloon material for highly calcified or rigid lesions*
- *Improved shaft design for short inflation- and deflation duration*



- Verstärktes Anschlussstück und weitere, speziell an die Anforderungen der TAVI angepasste Detaillösungen für höchste Flexibilität und Zuverlässigkeit
- *Improved Y-Connector and other details providing convenient handling and reliability for the special requirements of TAVI*

OSYPKA Zubehör für die Valvuloplastie & TAVI / Accessories for Valvuloplasty & TAVI



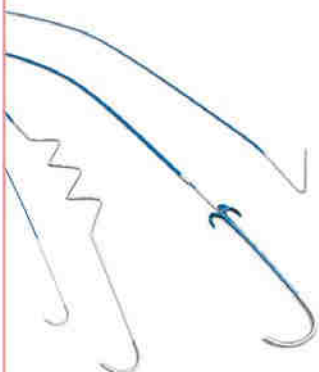
Externer Einkammer-Herzschrillmacher
Single-Chamber Pacemaker
PACE 101 H

Externer Zweikammer-Herzschrillmacher
Dual-Chamber Pacemaker
PACE 203 H



Temporäre Stimulationskatheter
Temporary pacing catheters

- Standard 2-pol. / *Standard 2-pol.* **TB**
- Einschwemmgesteuerter Stimulationskatheter / *Flow directed pacing catheter* **Helios™**



Temporäre epikardiale Myokardelektroden (Herzdrähte)
Temporary epicardial pacing wires
OSYPKA TME

Bestellinformationen / Ordering information:

Produkt- typ <i>Product Type</i>	Ballon-Ø <i>Balloon Ø</i> [mm]	Ballon Länge <i>Balloon length</i>					Arbeits- druck <i>Nominal pressure</i> [bar]	Maximal- druck <i>Rated burst pressure</i> [bar]	Empf. Führungsdraht <i>Recommended guide wire</i> [inch]	Schaft- größe <i>Shaft size</i> [F]	Empf. Schleuse <i>Rec. introducer</i> [F]	Nutzbare Länge <i>Usable length</i> [cm]
		20 mm	30 mm	40 mm	50 mm	60 mm						
VACS II - Low Profile Balloon, Small Introducer, Medium Pressure												
VACS® II	4	YA0010					4.5	6.0	0.021	4	4	70
VACS® II	5	YA0011					4.5	6.0	0.021	4	4	70
VACS® II	6	YA0012					3.5	4.0	0.021	4	4	70
VACS® II	7	YA0013	YA0014				3.5	4.0	0.021	4	4	70
VACS® II	8	YA0015	YA0016				3.5	4.0	0.021	4	4	70
VACS® II	9	YA0018	YA0019				3.0	3.5	0.025	5	5	90
VACS® II	10	YA0020	YA0021	YA0022			3.0	3.5	0.025	5	5	90
VACS® II	12	YA0023	YA0024				3.0	3.5	0.025	5	5	90
VACS® II	12			YA0025		YA0026	3.0	3.5	0.035	6	6	90
VACS® II	14		YA0027	YA0028	YA0029	YA0030	2.0	3.0	0.035	7	7	100
VACS® II	16		YA0035	YA0036	YA0037	YA0038	2.0	2.5	0.035	7	7	100
VACS® II	18		YA0043	YA0044	YA0045	YA0046	1.5	2.0	0.035	8	8	100
VACS® II	20		YA0047	YA0048	YA0049	YA0050	1.5	2.0	0.035	8	8	100
VACS® II	22		YA0051	YA0052	YA0053	YA0054	1.5	2.0	0.035	8	8	100
VACS® II	24		YA0055	YA0056		YA0057	1.0	1.5	0.035	9	9	100
VACS® II	26		YA0058	YA0059	YA0060	YA0061	1.0	1.5	0.035	9	9	100
VACS® II	28		YA0062	YA0063	YA0064	YA0065	1.0	1.5	0.035	9	10	100
VACS® II	30		YA0066	YA0067	YA0068	YA0069	1.0	1.5	0.035	9	10	100
VACS III - High Pressure Balloon, Fast Inflation												
VACS® III	5	YA30520					6.0	15.0	0.025	5	6	100
VACS® III	6	YA30620					6.0	15.0	0.025	5	6	100
VACS® III	7	YA30720					6.0	15.0	0.025	5	6	100
VACS® III	8	YA30820	YA30830				6.0	15.0	0.035	6	7	100
VACS® III	9	YA30920	YA30930				6.0	14.0	0.035	6	7	100
VACS® III	10	YA31020	YA31030	YA31040			6.0	13.0	0.035	6	7	100
VACS® III	12	YA31220	YA31230	YA31240		YA31260	6.0	10.0	0.035	6	8	100
VACS® III	14		YA31430	YA31440		YA31460	5.0	10.0	0.035	7	9	100
VACS® III	16		YA31630	YA31640		YA31660	4.0	8.0	0.035	7	9	100
VACS® III	18		YA31830	YA31840		YA31860	4.0	7.0	0.035	8	10	100
VACS® III	20			YA32040		YA32060	2.0	5.0	0.035	8	12	100
VACS® III	22			YA32240		YA32260	2.0	4.0	0.035	9	12	100
VACS® III	23			YA32340			2.0	4.0	0.035	9	14	100
VACS® III	24			YA32440		YA32460	2.0	4.0	0.035	12	14	100
VACS® III	25			YA32540			2.0	4.0	0.035	9	14	100
VACS® III	26			YA32640		YA32660	2.0	4.0	0.035	12	14	100
VACS® III	28			YA32840		YA32860	2.0	4.0	0.035	12	14	100
VACS® III	30			YA33040		YA33060	2.0	4.0	0.035	12	14	100



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

No. CE 598775
Issued To: Osypka AG
Earl-H.-Wood-Straße 1
Rheinfelden
79618
Germany

In respect of:

The design, development and manufacture of RF ablation catheters, multipolar steerable diagnostic catheters, diagnostic catheters for intracardiac recording and temporary pacing, valvuloplasty balloon catheters, endovascular grasping and snare/loop-catheters, TMA temporary pacing leads, external cardiac pacemaker and cardioversion devices and those aspects related to obtaining and maintaining sterility for temporary pacing lead adapters, cables DX, PK and TX, cables for EP catheters and cables for pacing leads.

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):



Albert Roossien, Regulatory Lead

First Issued: 2016-07-22

Date: 2019-02-27

Expiry Date: 2023-12-18

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.