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

Funcţia, numele, prenumele persoanei care a eliberat certificatul

semnătura

MD 0067985

L.Ş.

Digitally signed by Kojevnikov Dmitrii
Date: 2022.06.13 10:18:06 EEST
Reason: MoldSign Signature
Location: Moldova

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 pînă la Prelungită pînă 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 autentificată de autoritatea de licențiere, în care sînt indicate condițiile de licențiere pentru genul de activitate specificat în licență.

MOBIAS BANCA

Nr. 12101-504

18.03.2016

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.

L.Ş.

Dumitru Popa
Director filială „Stejaur"

Executor : Mariana Guzun
Tel: 022 812 614

Filiala Nr. 1 „Stejaur"
Bd. Ştefan cel Mare şi Sfânt 196
MD-2004, Chişinău, Moldova
Cod MOBBMD22
Cont de corespondenţă 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. Ştefan cel Mare şi Sfânt 81a
MD-2012, Chişinău, 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 vînzarea 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 **Lazari Aliona**
tel. 022-266-252

MINISTERUL JUSTIȚIEI AL REPUBLICII MOLDOVA * CAMERA ÎNREGISTRĂRII DE STAT Î.S. * 1004600077171 * 101 *

AA6 * EA * 0346843EA

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

EC Design Examination Certificate
Active Implantable Medical Devices Directive 90/385/EEC

*The National Standards Authority of Ireland as a duly designated Notified Body, (identification number **0050**), for the purposes of the European Communities (Medical Devices) Regulations (S.I. No. 253 of 1994)*

HAS EXAMINED THE DESIGN DOSSIER
Submitted by

Medtronic, Inc.

710 Medtronic Parkway
Minneapolis, MN 55432
USA

For Product Family

Heart Therapy Delivery Systems

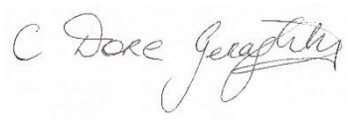
GMDN Code: 17846

CONCLUSION of EXAMINATION:

Complies with the requirements of Directive 90/385/EEC on Active Implantable Medical Devices Annex II (4)

Registration Number:	**253.100**
Original Approval:	**12 June 2002**
Last Amended on:	**03 March 2021**
Remains valid until:	**26 May 2024**

Signed:



Approved by:
Dr. Caroline Dore Geraghty
Director, Medical Devices

Approved by:
Dr. Elaine Darcy
European Medical Device Operations Manager

CONDITIONS OF VALIDITY:

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.

Approved model numbers are included in the associated attachment

Not valid without a valid Annex II Section 3 certificate

Note: Changes which could affect conformity with the essential requirements of Directive 90/385/EEC, or with the conditions prescribed for use of the product must receive further approval from NSAI.

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.

Attachment to Certificate 253.100 dated 12 June 2002

This Certificate covers 34 model(s)

File Ref	Model Reference	Detail
253.100.03 253.100.13 253.100.19 253.100.21 253.100.35	C304-S59	SelectSite™ C304-S59 Deflectable Catheter System
253.100.34 253.100.35	C304-HIS	SelectSite™ C304-HIS Deflectable Catheter system
253.100.03 253.100.13 253.100.19 253.100.21 253.100.35	C304-L69	SelectSite™ C304-L69 Deflectable Catheter System
253.100.13 253.100.19 253.100.21 253.100.35	C304-XL74	SelectSite™ C304-XL74 Deflectable Catheter System
253.100.13 253.100.19 253.100.35	6227DEF	Attain® 6227DEF Deflectable Catheter Delivery System
253.100.23 253.100.26 253.100.33 253.100.35	C315S4	C315S4 Delivery Catheter
253.100.23 253.100.26 253.100.33 253.100.35	C315S5	C315S5 Delivery Catheter
253.100.23 253.100.26 253.100.33 253.100.35	C315S10	C315S10 Delivery Catheter

Attachment to Certificate 253.100 dated 12 June 2002

This Certificate covers 34 model(s)

253.100.23 253.100.26 253.100.33 253.100.35	C315J	C315J Delivery Catheter
253.100.23 253.100.26 253.100.33 253.100.35	C315HIS	C315HIS Delivery Catheter
253.100.23 253.100.26 253.100.33 253.100.35	C315H20	C315H20 Delivery Catheter
253.100.23 253.100.26 253.100.33 253.100.35	C315H40	C315H40 Delivery Catheter
253.100.27 253.100.33 253.100.35	6250VIS	Attain Command™ + SureValve™ 6250VIS Left-Heart Delivery System
253.100.27 253.100.33 253.100.35	6250VIC	Attain Command™ + SureValve™ 6250VIC Left-Heart Delivery System
253.100.27 253.100.33 253.100.35	6250VI-MB2	Attain Command™ + SureValve™ 6250VI-MB2 Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-EH	Attain Command™ + SureValve™ 6250VI-EH Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-EHXL	Attain Command™ + SureValve™ 6250VI-EHXL Guide Catheter for Left-Heart Delivery

Attachment to Certificate 253.100 dated 12 June 2002

This Certificate covers 34 model(s)

253.100.27 253.100.33 253.100.35	6250VI-MPR	Attain Command™ + SureValve™ 6250VI-MPR Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-MP	Attain Command™ + SureValve™ 6250VI-MP Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-AM	Attain Command™ + SureValve™ 6250VI-AM Guide Catheter for Left Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-MB2X	Attain Command™ + SureValve™ 6250VI-MB2X Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-45S	Attain Command™ + SureValve™ 6250VI-45S Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-50S	Attain Command™ + SureValve™ 6250VI-50S Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-57S	Attain Command™ + SureValve™ 6250VI-57S Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-MPX	Attain Command™ + SureValve™ 6250VI-MPX Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-3D	Attain Command™ + SureValve™ 6250VI-3D Guide Catheter for Left-Heart Delivery

Attachment to Certificate 253.100 dated 12 June 2002

This Certificate covers 34 model(s)

253.100.27 253.100.35 253.100.36	6248VI-90	Attain Select™ II + SureValve™ 6248VI-90 Delivery Catheter System
253.100.27 253.100.35 253.100.36	6248VI-90S	Attain Select™ II + SureValve™ 6248VI-90S Delivery Catheter System
253.100.27 253.100.35 253.100.36	6248VI-90L	Attain Select™ II + SureValve™ 6248VI-90L Delivery Catheter System
253.100.27 253.100.35 253.100.36	6248VI-130	Attain Select™ II + SureValve™ 6248VI-130 Delivery Catheter System
253.100.27 253.100.35 253.100.36	6248VI-130L	Attain Select™ II + SureValve™ 6248VI-130L Delivery Catheter System
253.100.27 253.100.35 253.100.36	6248VI-90P	Attain Select™ II + SureValve™ 6248VI-90P Delivery Catheter System
253.100.27 253.100.35 253.100.36	6248VI-90SP	Attain Select™ II + SureValve™ 6248VI-90SP Delivery Catheter System
253.100.27 253.100.35 253.100.36	6248VI-130P	Attain Select™ II + SureValve™ 6248VI-130P Delivery Catheter System

Quality System Approval Certificate
Active Implantable Medical Devices Directive 90/385/EEC

*The National Standards Authority of Ireland as a duly designated Notified Body, (identification number **0050**), for the purposes of the European Communities (Medical Devices) Regulations (S.I. No. 253 of 1994)*

APPROVES THE QUALITY SYSTEM APPLIED BY

Medtronic, Inc.

710 Medtronic Parkway
Minneapolis, MN 55432
USA

For the Product Family

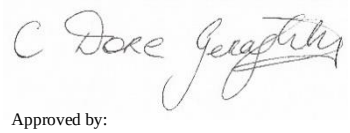
Heart Therapy Delivery Systems

GMDN Code: 17846

On the basis of examination under the requirements of Annex II, Section 3 of Directive 90/385/EEC,
The use of the NSAI Notified Body identification number **0050** in conjunction with CE Marking of Conformance for this product is hereby authorized.

Registration Number:	**253.100**
Original Approval:	**12 June 2002**
Last Amended on:	**03 March 2021**
Remains valid until:	**26 May 2024**

Signed:



Approved by:
Dr. Caroline Dore Geraghty
Director, Medical Devices

Approved by:
Dr. Elaine Darcy
European Medical Device Operations Manager

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.
Details of the current product range and operational locations included within the scope of this approval can be obtained from NSAI.
This certificate must be supported by a valid design examination certificate.

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.

EC Design-Examination Certificate

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

No. **CE 634279**

Issued To: **Osypka AG**
Earl-H.-Wood-Straße 1
Rheinfelden
79618
Germany

In respect of:

VACS Percutaneous Transluminal Valvuloplasty Catheter

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. 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: **2016-07-22** Date: **2020-06-04** Expiry Date: **2024-05-26**

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EC Design-Examination Certificate

Supplementary Information to CE 634279

Issued To:

Osypka AG
Earl-H.-Wood-Straße 1
Rheinfelden
79618
Germany

Intended purpose per IFU: This product is recommended for percutaneous transluminal valvuloplasty. Possible indications: Outflow tract - stenosis of the right and left ventricle, Pulmonary valve stenosis, Aortic valve stenosis, Peripheral pulmonary artery stenosis, Aortic isthmus stenosis, Aortic valve pre-dilation prior to TAVI procedures.

Classification: Class III

Catalogue Number	Device Name	Model, Type
YA0010	VACS II	4.0 x 20
YA0011	VACS II	5.0 x 20
YA0012	VACS II	6.0 x 20
YA0013	VACS II	7.0 x 20
YA0014	VACS II	7.0 x 30
YA0015	VACS II	8.0 x 20
YA0016	VACS II	8.0 x 30
YA0018	VACS II	9.0 x 20
YA0019	VACS II	9.0 x 30
YA0020	VACS II	10.0 x 20
YA0021	VACS II	10.0 x 30
YA0022	VACS II	10.0 x 40
YA0023	VACS II	12.0 x 20
YA0024	VACS II	12.0 x 30
YA0025	VACS II	12.0 x 40

First Issued: **2016-07-22** Date: **2020-06-04** Expiry Date: **2024-05-26**

EC Design-Examination Certificate

Supplementary Information to CE 634279

Issued To:

Osypka AG
Earl-H.-Wood-Straße 1
Rheinfelden
79618
Germany

Catalogue Number	Device Name	Model, Type
YA0026	VACS II	12.0 x 60
YA0027	VACS II	14.0 x 30
YA0028	VACS II	14.0 x 40
YA0029	VACS II	14.0 x 50
YA0030	VACS II	14.0 x 60
YA0031	VACS II	15.0 x 30
YA0032	VACS II	15.0 x 40
YA0033	VACS II	15.0 x 50
YA0034	VACS II	15.0 x 60
YA0035	VACS II	16.0 x 30
YA0036	VACS II	16.0 x 40
YA0037	VACS II	16.0 x 50
YA0038	VACS II	16.0 x 60
YA0039	VACS II	17.0 x 30
YA0040	VACS II	17.0 x 40
YA0041	VACS II	17.0 x 50
YA0042	VACS II	17.0 x 60
YA0043	VACS II	18.0 x 30

Catalogue Number	Device Name	Model, Type
YA0044	VACS II	18.0 x 40
YA0045	VACS II	18.0 x 50
YA0046	VACS II	18.0 x 60
YA0047	VACS II	20.0 x 30
YA0048	VACS II	20.0 x 40
YA0049	VACS II	20.0 x 50
YA0050	VACS II	20.0 x 60
YA0051	VACS II	22.0 x 30
YA0052	VACS II	22.0 x 40
YA0053	VACS II	22.0 x 50
YA0054	VACS II	22.0 x 60
YA0055	VACS II	24.0 x 30
YA0056	VACS II	24.0 x 40
YA0057	VACS II	24.0 x 60
YA0058	VACS II	26.0 x 30
YA0059	VACS II	26.0 x 40
YA0060	VACS II	26.0 x 50
YA0061	VACS II	26.0 x 60

First Issued: **2016-07-22** Date: **2020-06-04** Expiry Date: **2024-05-26**

EC Design-Examination Certificate

Supplementary Information to CE 634279

Issued To:

Osypka AG
Earl-H.-Wood-Straße 1
Rheinfelden
79618
Germany

Catalogue Number	Device Name	Model, Type
YA0062	VACS II	28.0 x 30
YA0063	VACS II	28.0 x 40
YA0064	VACS II	28.0 x 50
YA0065	VACS II	28.0 x 60
YA0066	VACS II	30.0 x 30
YA0067	VACS II	30.0 x 40
YA0068	VACS II	30.0 x 50
YA0069	VACS II	30.0 x 60
YA30520	VACS III	5.0 x 20
YA30620	VACS III	6.0 x 20
YA30720	VACS III	7.0 x 20
YA30820	VACS III	8.0 x 20
YA30830	VACS III	8.0 x 30
YA30920	VACS III	9.0 x 20
YA30930	VACS III	9.0 x 30
YA31020	VACS III	10.0 x 20
YA31030	VACS III	10.0 x 30
YA31040	VACS III	10.0 x 40

Catalogue Number	Device Name	Model, Type
YA31220	VACS III	12.0 x 20
YA31230	VACS III	12.0 x 30
YA31240	VACS III	12.0 x 40
YA31260	VACS III	12.0 x 60
YA31430	VACS III	14.0 x 30
YA31440	VACS III	14.0 x 40
YA31460	VACS III	14.0 x 60
YA31530	VACS III	15.0 x 30
YA31540	VACS III	15.0 x 40
YA31630	VACS III	16.0 x 30
YA31640	VACS III	16.0 x 40
YA31660	VACS III	16.0 x 60
YA31830	VACS III	18.0 x 30
YA31840	VACS III	18.0 x 40
YA31860	VACS III	18.0 x 60
YA32040	VACS III	20.0 x 40
YA32050	VACS III	20.0 x 50
YA32060	VACS III	20.0 x 60

First Issued: **2016-07-22** Date: **2020-06-04** Expiry Date: **2024-05-26**

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EC Design-Examination Certificate

Supplementary Information to CE 634279

Issued To:

Osypka AG
Earl-H.-Wood-Straße 1
Rheinfelden
79618
Germany

Catalogue Number	Device Name	Model, Type
YA32240	VACS III	22.0 x 40
YA32250	VACS III	22.0 x 50
YA32260	VACS III	22.0 x 60
YA32340	VACS III	23.0 x 40
YA32350	VACS III	23.0 x 50
YA32360	VACS III	23.0 x 60
YA32440	VACS III	24.0 x 40
YA32460	VACS III	24.0 x 60
YA32540	VACS III	25.0 x 40
YA32550	VACS III	25.0 x 50
YA32560	VACS III	25.0 x 60
YA32640	VACS III	26.0 x 40
YA32660	VACS III	26.0 x 60
YA32840	VACS III	28.0 x 40
YA32860	VACS III	28.0 x 60
YA33040	VACS III	30.0 x 40
YA33060	VACS III	30.0 x 60

First Issued: **2016-07-22** Date: **2020-06-04** Expiry Date: **2024-05-26**

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EC Design-Examination Certificate

Supplementary Information to CE 634279

Issued To:

Osypka AG
Earl-H.-Wood-Straße 1
Rheinfelden
79618
Germany

Certificate History

Date	Reference Number	Action
22 July 2016	10161066	First Issue – Transfer from another Notified Body.
29 January 2019	9630089	Changes to the laser welding process and balloon folding process. IFU update (change of retraction rotation direction).
27 February 2019	8586436	Traceable to NB 0086.
Current	9758242	Certificate Renewal. Addition of subcontractor "Osypka s.r.o, Odry – Czech Republic" for the activity of manufacturing. Update of supplementary information page to include intended purpose per IFU and device classification as per current BSI template. Reformatting of device models table.

First Issued: **2016-07-22** Date: **2020-06-04** Expiry Date: **2024-05-26**

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Osypka AG
Earl-H.-Wood-Straße 1
Rheinfelden
79618
Germany

Holds Certificate Number: **MD 613632**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, development, manufacturing, assembling and maintenance of medical devices for temporary stimulation and electrophysiology, permanent stimulation, HF-Ablation, interventional cardiology, medical components, neurology and contract sterilization services in accordance with EN ISO 11135:2014+A1:2019.
Design, Entwicklung, Produktion, Montage und Wartung von Medizinprodukten aus den Bereichen Temporäre Stimulation und Elektrophysiologie, Permanente Stimulation, HF-Ablation, Interventionelle Kardiologie, Medical Components, Neurologie und Lohnsterilisation von Medizinprodukten nach EN ISO 11135:2014+A1:2019 als Dienstleistung.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2016-06-30
Effective Date: 2021-03-11
Latest Revision Date: 2021-09-08
Expiry Date: 2024-03-10

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Certificate No: **MD 613632**

Location	Registered Activities
Osypka AG Earl-H.-Wood-Straße 1 Rheinfelden 79618 Germany	Design, development, manufacturing, assembling and maintenance of medical devices for temporary stimulation and electrophysiology, permanent stimulation, HF-Ablation, interventional cardiology, medical components, neurology and contract sterilization services in accordance with EN ISO 11135:2014+A1:2019. Design, Entwicklung, Produktion, Montage und Wartung von Medizinprodukten aus den Bereichen Temporäre Stimulation und Elektrophysiologie, Permanente Stimulation, HF-Ablation, Interventionelle Kardiologie, Medical Components, Neurologie und Lohnsterilisation von Medizinprodukten nach EN ISO 11135:2014+A1:2019 als Dienstleistung.
Osypka AG Gottlieb-Daimler-Str. 5 Rheinfelden 79618 Germany	Design, development, manufacturing, assembling and maintenance of medical devices for temporary stimulation and electrophysiology, permanent stimulation, HF-Ablation, interventional cardiology, medical components, neurology and contract sterilization services in accordance with EN ISO 11135:2014+A1:2019 Design, Entwicklung, Produktion, Montage und Wartung von Medizinprodukten aus den Bereichen Temporäre Stimulation und Elektrophysiologie, Permanente Stimulation, HF-Ablation, Interventionelle Kardiologie, Medical Components, Neurologie und Lohnsterilisation von Medizinprodukten nach EN ISO 11135:2014+A1:2019 als Dienstleistung.

Original Registration Date: 2016-06-30

Effective Date: 2021-03-11

Latest Revision Date: 2021-09-08

Expiry Date: 2024-03-10

PACE 101 H / PACE 203 H / PACE 300

External Cardiac Pacemakers

+++

Externer Demand-Herzschrittmacher
External Demand Pacemaker

Externer Zweikammer-Herzschrittmacher
External Dual Chamber Pacemaker

Externer Dreikammer-Herzschrittmacher
External Triple Chamber Pacemaker

OSYPKA
Technology for an active life

PACE 203 H

Handliches Design, einfache und schnelle Bedienung durch Dreh- und Druckknöpfe /
Handy design, simple and quick handling by control and press button

PAUSE-Funktion / ***PAUSE-Function*:**
Darstellung der intrinsische Signalstärke und Frequenz in Atrium & Ventrikel, sowie spontanes AVD /
Display of intrinsic atrial and ventricular signals including AVD

Besondere Eigenschaften:

- **NEU!** Darstellung von **Elektrodenimpedanz** (Ohm) und **Stromstärke** (mA) ; Firmware 1.30*
- Automatikfunktionen bei AV-Delay, PVARP, MTR und Empfindlichkeit - besonders geeignet für pädriatische Anwendungen
- Atrial Trigger auch im DDD-Modus
- Displaybeleuchtung (optional ausschaltbar)
- Sicherung gegen Cross-Talk und Defi-Schock
- Einstellungen können gespeichert werden
- Statistik über Wahrnehmungs- und Stimulations-ereignisse
- Rapid Ventricular Pacing (bis 220ppm) für TAVI Proze-dur und Atriales High Rate (bis 1000 ppm)
- Verpolschutz beim Einsetzen der Batterie
- Backup Pacing durch interne Energiespeicher
- schnellstes „Power on to work“ < 2 Sek.
- Prüfung der Elektrodenintegrität und Aufzeigen von EM Störungen
- Emergency Mode durch Tastendruck für Notfallsituationen
- Externes Netzgerät optional erhältlich
- Schnittstelle zu Hämodynamik Monitor AESCULON® (Pacemaker Clinic™)
- Lange Batterielebensdauer

Special Features:

- ***New!** Display of* **Lead impedance** *(Ohm) and* **electrical current** *(mA) , Firmware 1.30**
- *Automatic functions for AV-Delay, PVARP, MTR, and sensitivity - especially suited for pediatric applications*
- *Atrial trigger also in DDD mode*
- *Display illumination (can be switched off optionally)*
- *Safe against cross talk and defibrillator shock*
- *Settings can be stored*
- *Display of statistic of sensing and pacing events*
- *Rapid Ventricular Pacing (up to 220ppm) for TAVI procedure and atrial high Rate (up to 1000 ppm)*
- *Battery: Reverse polarity insertion protection*
- *Backup Pacing through internal energy storage*
- *fastest „Power on to work“ < 2 sec.*
- *Test of lead integrity and display of EM interference*
- *Emergency Mode button*
- *External power supply cable available (optional)*
- *Interface to hemodynamic monitor AESCULON® (Pace-maker Clinic™)*
- *Long battery life*

Technische Daten:

- Modi: DDD, VDD, D00, VVI, V00, AAI, AAT, A00, DVI, DAI, VAT, DDD+AT, DAT
- Grundfrequenz 30 …220 ppm
- Obere Frequenzbegrenzung 80 … 230 ppm
- Overdrive-Stimulation (atrial) 70 … 1000 ppm
- Ventrikuläres Rapid Pacing 180 … 220 ppm
- Stimulationsamplituden 0,1 … 18 V
- Impulsdauer 0,05 … 1,5 ms
- Empfindlichkeit atrial 0,2 … 20 mV, ∞
ventrikulär 1,0 … 20 mV, ∞
- Refraktärzeit atrial 250 … 400 ms
PVARP 100 … 500 ms
ventrikulär 200 … 500 ms
- AV-Delay 5 … 400 ms
- Gewicht mit Batterie 490 g

Technical Data:

- *Modes: DDD, VDD, D00, VVI, V00, AAI, AAT, A00, DVI, DAI, VAT, DDD+AT, DAT*
- *Basic rate 30 …220 ppm*
- *Maximum Tracking Rate (MTR) 80 … 230 ppm*
- *Overdrive stimulation (atrial) 70 … 1000 ppm*
- *Ventricular Rapid Pacing 180 … 220 ppm*
- *Stimulation amplitude 0.1 … 18 V*
- *Pulse duration 0.05 … 1.5 ms*
- *Sensitivity atrial 0.2 … 20 mV, ∞
ventricular 1.0 … 20 mV, ∞*
- *Refractory period atrial 250 … 400 ms
PVARP 100 … 500 ms
ventricular 200 … 500 ms*
- *AV-Delay 5 … 400 ms*
- *Weight with battery 490 g*

PACE 101 H

Overdrive-Stimulation durch Verdopplung bzw. Vervierfachung der Stimulationsfrequenz zur Terminierung von atrialen Tachykardien / *Over-drive stimulation for termination of atrial tachycardia through quick increase (x2, x4) of the stimulation frequency*

Berührungsgeschützte Spannzangen für Stecker mit 0,9-2,0 mm Durchmesser / *Touch-protected connection terminals with 0,9 - 2,0mm diameter*

Sensitivity Dial

Basic Rate Dial

LED Indicator: Low Battery/Error

Sensing Indicator

Stimulation Amplitude Dial

Mode Dial: On/Off, Acoustic Signal, Stimulation Frequency (x2, x4)

Rapid Atrial Pacing Button

Einstellung der Parameter per Knopf / *Settings of the parameter by button*

Batterieüberwachung mit akustischer und optischer Warnanzeige / *Battery monitoring with acoustic and optical warning*

Technische Daten:

- Modi: A00, AAI, V00, VVI
- Grundfrequenz 30 …180 ppm
- Overdrive-Stimulation: async., freq. x2, x4
- Stimulationsamplituden 0,3 … 12 V
- Impulsdauer 0,75 ms
- Empfindlichkeit 1,0 … 20 mV, ∞
- Refraktärzeit 250 ms
- Gewicht mit Batterie 170 g

Technical Data:

- *Modes: A00, AAI, V00, VVI*
- *Basic rate 30 …180 ppm*
- *High rate: async., freq. x2, x4*
- *Stimulation amplitude 0.3 … 12 V*
- *Pulse duration 0.75 ms*
- *Sensitivity 1.0 … 20 mV, ∞*
- *Refractory period 250 ms*
- *Weight with battery 170 g*

Stand: 10/2014

PACE 300

Besondere Eigenschaften (zusätzlich zu den Funktionen des PACE 203H):

- Individuelle Einstellung des VV-Delays (Stimulations-Amplitude sowie Wahrnehmung)

V-V Delay Einstellung zur temporären Biventrikulären Stimulation (CRT) zur post-operativen hämodynamischen Optimierung Herzchirurgischer Patienten*

Special Features (additional to the features of PACE 203H):

- *Variable setting of VV-Delay (pacing threshold as well as sensitivity)*

*Setting of the V-V Delay for temporary biventricular stimulation (CRT) to optimize post-operative hemodynamics of cardiac surgery patients**

Bestellinformationen / *Ordering information*:

Artikel-Nr. *Article No.*	Bezeichnung *Name*	Beschreibung *Description*
61216	PACE 101 H	Externer Einkammer-Herzschrittmacher | *External Single-Chamber-Pacemaker*
61225-ST	PACE 203 H	Externer Zweikammer-Herzschrittmacher | *External Dual-Chamber-Pacemaker*
61227-ST	PACE 300	Externer Dreikammer-Herzschrittmacher | *External Triple-Chamber-Pacemaker*

Zubehör / *Accessories*:

Artikel-Nr. *Article No.*	Bezeichnung *Name*	Beschreibung *Description*
81973	D2-SP	Universal-Verlängerungskabel grau / *universal extention cable grey, 2,50 m*
81986BL	D2P-SP	Verlängerungskabel blau (Farbkennung HSM Atrium) / *Extension Cable blue* (color coding PM Atrium), 2,50 m
81986WS	D2P-SP	Verlängerungskabel weiß (Farbkennung HSM Ventrikel) / *Extension Cable white (color coding PM ventricle), 2,50 m*
61514		Netzteil EU / *power supply EU*
82105		Ballonpumpen Interface BPI 202 / *Balloon pump interface BPI 202*
85020	Armbinde *Armstrap*	Armbinde mit Klettverschluss, 45 cm *Armstrap with velcro fastener, 45 cm*

Rufen Sie uns an bezüglich / *Call us for*:

Artikel-Nr. *Article No.*	Bezeichnung *Name*	Beschreibung *Description*
(...)		verschiedene OSYPKA - Temporäre Myokard Elektroden (Herzchirurgie) / *sev. Temporary Myocardial Leads*
(...)		verschiedene OSYPKA - Temporäre Stimulationskatheter (Kardiologie) / *sev. Temporary Pacing Catheters*

Gebrauchsanleitung beachten
Consult instructions for use

* Bitte kontaktieren Sie unser Produktmanagement betreffs Literaturnachweisen.
For literature references please contact our product management.

OSYPKA
Technology for an active life

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