Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 2 din 13.10.2023

Solicitantul SRL Biosistem mld, cu sediul str. Albișoara 16/1 of.7, or. Chișinău
(adresa)
Tel./Fax: .+373-22-808517, +373-22-808719, fax +373-22-808519, e-mail biosistem.mld@gmail.com; info@biosistem-mld.com, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

- Percutaneous Transluminal Valvuloplasty Catheter

Se anexează următoarele acte:
Declaraţie pe proprie răspundere
CE certificate
Declaratie de conformitate
Scrisoare de imputernicire

Digitally signed by Poiata Vitalie
Date: 2023.10.13 17:09:17 EEST
Reason: MoldSign Signature
Location: Moldova

Data 13.10.2023 Semnătura _____

Tabelul de recepționare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Digitally signed by Kojevnikov Dmitrii
Date: 2023.10.13 17:11:12 EEST
Reason: MoldSign Signature
Location: Moldova

Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: SRL Biosistem mld, cu sediul str. Albișoara 16/1 of.7, or. Chișinău, declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

- Percutaneous Transluminal Valvuloplasty Catheter

Sunt autentice și corespund realității.

Administrator: Poiata Vitalie *Semnătura* _____

Data 13.10.2023

OSYPKA
Technology for an active life
A company of the Peter Osypka Foundation

To: Whomever it may concern

Biosistem-mld SRL
Albisoara 16/1 ap.7
Chisinau, R. Moldova

Rheinfelden, 10.10.2023

MANUFACTURERS AUTHORIZATION

We, OSYPKA AG manufacturer of medical products with principal place of business at Earl-H.-Wood-Strasse 1, 79618 Rheinfelden, Germany hereby confirm that **Biosistem mld SRL** with business office at Albisoara 16/1 ap.7, Chisinau, Republic of Moldova, is authorized to carry out the registration of products manufactured by our company in the Ministry of Health of Republic of Moldova.

This authorization is valid for 3 years from the date of issuance and automatically renewable if no termination letter is issued.

Yours sincerely,

Ilse Karin Kastner
VP Sales
OSYPKA AG

OSYPKA AG
Medizintechnik
Earl-H.-Wood-Strasse 1
D-79618 Rheinfelden

We

OSYPKA AG

Earl-H.-Wood-Straße 1

D-79618 Rheinfelden - Herten

declare under our sole responsibility, that the class III medical device

VACS

Percutaneous Transluminal Valvuloplasty Catheter

Catalogue Number	Designation	Catalogue Number	Designation
YA0010	VACS II 4.0 x 20	YA30520	VACS III 5.0 x 20
YA0011	VACS II 5.0 x 20	YA30620	VACS III 6.0 x 20
YA0012	VACS II 6.0 x 20	YA30720	VACS III 7.0 x 20
YA0013	VACS II 7.0 x 20	YA30820	VACS III 8.0 x 20
YA0014	VACS II 7.0 x 30	YA30830	VACS III 8.0 x 30
YA0015	VACS II 8.0 x 20	YA30920	VACS III 9.0 x 20
YA0016	VACS II 8.0 x 30	YA30930	VACS III 9.0 x 30
YA0018	VACS II 9.0 x 20	YA31020	VACS III 10.0 x 20
YA0019	VACS II 9.0 x 30	YA31030	VACS III 10.0 x 30
YA0020	VACS II 10.0 x 20	YA31040	VACS III 10.0 x 40
YA0021	VACS II 10.0 x 30	YA31220	VACS III 12.0 x 20
YA0022	VACS II 10.0 x 40	YA31230	VACS III 12.0 x 30
YA0023	VACS II 12.0 x 20	YA31240	VACS III 12.0 x 40
YA0024	VACS II 12.0 x 30	YA31260	VACS III 12.0 x 60
YA0025	VACS II 12.0 x 40	YA31430	VACS III 14.0 x 30
YA0026	VACS II 12.0 x 60	YA31440	VACS III 14.0 x 40
YA0027	VACS II 14.0 x 30	YA31460	VACS III 14.0 x 60
YA0028	VACS II 14.0 x 40	YA31530	VACS III 15.0 x 30
YA0029	VACS II 14.0 x 50	YA31540	VACS III 15.0 x 40
YA0030	VACS II 14.0 x 60	YA31630	VACS III 16.0 x 30
YA0031	VACS II 15.0 x 30	YA31640	VACS III 16.0 x 40
YA0032	VACS II 15.0 x 40	YA31660	VACS III 16.0 x 60
YA0033	VACS II 15.0 x 50	YA31830	VACS III 18.0 x 30
YA0034	VACS II 15.0 x 60	YA31840	VACS III 18.0 x 40
YA0035	VACS II 16.0 x 30	YA31860	VACS III 18.0 x 60
YA0036	VACS II 16.0 x 40	YA32040	VACS III 20.0 x 40
YA0037	VACS II 16.0 x 50	YA32050	VACS III 20.0 x 50
YA0038	VACS II 16.0 x 60	YA32060	VACS III 20.0 x 60
YA0039	VACS II 17.0 x 30	YA32240	VACS III 22.0 x 40
YA0040	VACS II 17.0 x 40	YA32250	VACS III 22.0 x 50
YA0041	VACS II 17.0 x 50	YA32260	VACS III 22.0 x 60
YA0042	VACS II 17.0 x 60	YA32340	VACS III 23.0 x 40
YA0043	VACS II 18.0 x 30	YA32350	VACS III 23.0 x 50

OSYPKA AG
Medizintechnik

Earl-H.-Wood-Straße 1
79618 Rheinfelden, Germany
Tel. 0 76 23 / 74 05 - 0
Fax 0 76 23 / 74 05 - 160

Catalogue Number	Designation	Catalogue Number	Designation
YA0044	VACS II 18.0 x 40	YA32360	VACS III 23.0 x 60
YA0045	VACS II 18.0 x 50	YA32440	VACS III 24.0 x 40
YA0046	VACS II 18.0 x 60	YA32460	VACS III 24.0 x 60
YA0047	VACS II 20.0 x 30	YA32540	VACS III 25.0 x 40
YA0048	VACS II 20.0 x 40	YA32550	VACS III 25.0 x 50
YA0049	VACS II 20.0 x 50	YA32560	VACS III 25.0 x 60
YA0050	VACS II 20.0 x 60	YA32640	VACS III 26.0 x 40
YA0051	VACS II 22.0 x 30	YA32660	VACS III 26.0 x 60
YA0052	VACS II 22.0 x 40	YA32840	VACS III 28.0 x 40
YA0053	VACS II 22.0 x 50	YA32860	VACS III 28.0 x 60
YA0054	VACS II 22.0 x 60	YA33040	VACS III 30.0 x 40
YA0055	VACS II 24.0 x 30	YA33060	VACS III 30.0 x 60
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		
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		

according to EC-Design Examination Certificate No. 634279, issued by the Notified Body No. 2797, the BSI Group Netherlands, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam and valid until 26.05.2024, is in conformity with the act on Medical Devices, the Medical Device Directive 93/42/EEC and the applicable standards and regulations.

This Declaration of Conformity covers all lots of the above mentioned device manufactured in our company within the validity period of the EC-Design Examination Certificate and which are labelled with the CE-mark.

Made in Germany
OSYPKA AG
Medizintechnik
Earl-H.-Wood-Straße 1
79618 Rheinfelden, Germany
Tel. 0 76 23 / 74 05 - 0
Fax 0 76 23 / 74 05 - 160

This Declaration of Conformity is supported by the Full Quality Assurance System certification according to Directive 93/42/EEC, Annex II for medical devices with the registration number 598775 issued by the Notified Body No. 2797, the BSI Group Netherlands, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam.

Rheinfelden-Herten, 08th of June 2020

Achim Kitschmann	Wilfred Heiner	Guido Derjung
CEO	*Core Team Manager*	*COO*

Technology for an active Life

Made in Germany

OSYPKA AG
Medizintechnik

Earl-H.-Wood-Straße 1
79618 Rheinfelden, Germany
Tel. 0 76 23 / 74 05 - 0
Fax 0 76 23 / 74 05 - 160

By Royal Charter

EC Certificate - Full Quality Assurance System

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, sterile 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):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2016-07-22** Date: **2021-05-06** Expiry Date: **2023-12-18**

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 598775

Issued To:

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

NBOG code(s)	Device Description	Intended purpose
Class III		
MD 0106 MDS 7006	VACS Percutaneous Transluminal Valvuloplasty Catheter	See CE 634279
MD 0106 MDS 7006	TME temporary pacing leads	See CE 666167
MD 0106 MDS 7006	TMA temporary atrial pacing leads	See CE 647672
MD 0106 MDS 7006	Sirius catheters for intracardiac recording and temporary pacing	See CE 659619
MD 1104 MDS 7006	Cerablate flutter RF Ablation catheters	See CE 598776
MD 1104 MDS 7006	CERABLATE® easy / easy TC RF Ablation catheters	See CE 659621
MD 1104 MDS 7006	Cerablate Cool Steerable Ablation Catheter with irrigated tip	See CE 607672

First Issued: **2016-07-22** Date: **2021-05-06** Expiry Date: **2023-12-18**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 598775

Issued To:

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

NBOG code(s)	Device Description	Intended purpose
Class IIb		
MD 1103 MDS 7010	External Pacemaker and Defibrillator	To be used with cardiac stimulation lead systems for temporary atrial, ventricular or AV sequential stimulation
Class Is		
MDS 7006	Cables for EP catheters	N/A
MDS 7006	Cables for pacing leads	N/A
MDS 7006	Lead adapters	N/A

First Issued: **2016-07-22** Date: **2021-05-06** Expiry Date: **2023-12-18**

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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 598775**
Date:	**2021-05-06**
Issued To:	**Osypka AG** **Earl-H.-Wood-Straße 1** **Rheinfelden** **79618** **Germany**

Subcontractor:	**Service(s) supplied**
Corscience GmbH & Co. KG HartmannstraBe 65 Erlangen 91052 Germany	**Development** **Manufacture**
Fort Wayne Metals Research Products Corporation 9609 Ardmore Avenue Fort Wayne Indiana 46809 USA	**Crucial Supplier**
Lake Region Medical 13024 North Main Street Trenton Georgia 30752 USA	**Crucial Supplier**

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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 598775**
Date:	**2021-05-06**
Issued To:	**Osypka AG** **Earl-H.-Wood-Straße 1** **Rheinfelden** **79618** **Germany**

Subcontractor:	**Service(s) supplied**
OEM Medical Component GmbH Basler-St.109 Grenzach-Wyhlen 79639 Germany	**Manufacture**
Osypka AG Gottlieb-Daimler-Str. 5 79618 Rheinfelden Germany	**ETO Sterilization** **Manufacture**
Osypka s.r.o Skřivánčí 1112/25 742 35 Odry Czech Republic	**Manufacture**
Teleflex Medical OEM Annacotty Business Park Annacotty Limerick Ireland	**Crucial Supplier**

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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 598775**
Date:	**2021-05-06**
Issued To:	**Osypka AG** **Earl-H.-Wood-Straße 1** **Rheinfelden** **79618** **Germany**

Subcontractor:	**Service(s) supplied**
Vereinigte Papierwarenfabriken GmbH Industriestr. 6 Feuchtwangen 91555 Germany	**Crucial Supplier**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 598775**
Date: **2021-05-06**
Issued To: **Osypka AG**
Earl-H.-Wood-Straße 1
Rheinfelden
79618
Germany

Date	Reference Number	Action
22 July 2016	8469215	First Issue – Transfer from another Notified Body.
07 November 2016	8588685	Addition of TMA temporary atrial pacing leads to the scope.
16 February 2017	8678379	Extension of scope to include TME temporary pacing leads, temporary pacing lead adapters, cables PK, cables for EP catheters and cables for pacing leads following a transfer from another Notified Body.
28 June 2017	8747148	Removal of subcontractor Coveris Flexibles Deutschland GmbH. Addition of subcontractor Teleflex Medical OEM for the activity crucial supplier.
08 August 2017	8630654	Extension of scope to include external cardiac pacemaker and cardioversion devices. Subcontractor name change from Accellent Cardiology, to Lake Region Medical, Inc.
17 December 2018	8900026	Certificate renewal. Change Lake Region Medical address from 6420 Zane Ave. North Brooklyn Park, Minnesota to 13024 North Main Street Trenton, Georgia. Change Fort Wayne Metals 9609 Indianapolis Road, Fort Wayne, Indiana to Fort Wayne Metals Research Products Corporation 9609 Ardmore Avenue, Fort Wayne, Indiana. Add device table.
27 February 2019	8586436	Traceable to NB 0086.

By Royal Charter

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 598775**
Date: **2021-05-06**
Issued To: **Osypka AG**
Earl-H.-Wood-Straße 1
Rheinfelden
79618
Germany

Date	Reference Number	Action
20 July 2020	3249093	Correction of the error introduced on 28 June 2017 (Reference number 8747148) and change back the scope from "TMA temporary pacing leads" to "sterile temporary pacing leads". Correction of the service supplied for the manufacturer Osypka s.r.o. – Czech Republic – from "Crucial Supplier" to "Manufacture".
Current	3334937	Reduction of scope to remove "endovascular grasping and snare/loop-catheters". Removal of products: -Finder, Finder pure and Woxx diagnostic catheters for intracardiac recording and temporary pacing -SIRIUS flutter catheters for the temporary ECG recording and for the stimulation of the heart with an external pacemaker -LASSOS Snare catheters and CATCHER Forceps catheter. Change Osypka s.r.o. address from tř Osvobození 273/30, 742 35 Odry to Skřivánčí 1112/25, 742 35 Odry.

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**

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EC Design-Examination Certificate

Supplementary Information to CE 634279

Issued To:

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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
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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
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

Supplementary Information to CE 634279 - Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3

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

Date: 17 February 2022

Changes Approved:

Date	Reference Number	Action
17 February 2022	3563772	Transfer of manufacturing activities from OSYPKA AG, Gottlieb-Daimler-Str. 5, Rheinfelden, Germany to Start-up Accelerator GmbH, Gottlieb-Daimler-Str. 2, Rheinfelden, Germany.

Inspiring trust for a more resilient world.

17 February 2022

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

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 634279	93/42/EEC Annex II Section 4	3563772	Relocation of core manufacturing activities from OSYPKA AG, Gottlieb-Daimler-Str. 5, Rheinfelden, Germany to Start-up Accelerator GmbH, Gottlieb-Daimler-Str. 2, Rheinfelden, Germany. Locations for manufacturing of subassembly Y-Piece, incoming inspection, injection molding, extrusion, sterilization, labelling, and shipping remain unchanged.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Gary Slack
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