

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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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.

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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

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
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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

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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

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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

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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.

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