EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 729271 R000

Manufacturer: Osypka AG

Address:
Earl-H.-Wood-Str. 1
79618 Rheinfelden
Germany

Single Registration Number: DE-MF-000005610

Digitally signed by Poiata Vitalie
Date: 2025.09.11 15:12:54 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

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

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2022-04-19**

Current Issue Date: **2025-01-23**

Starting Validity Date: **2025-01-23**

Expiry Date: **2027-04-18**

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Device Schedule: Class III devices and Class IIb devices

Class III	Intended purpose
TME Temporary Myocardial Electrode	See MDR 753215
TMA Temporary Myocardial Electrodes for Atrial Pacing and Cardioversion	See MDR 753211
CERABLATE® easy / easy TC	See MDR 753206
VACS II/III Gen 2 - percutaneous transluminal valvuloplasty catheters	See MDR 785847
MAGiC™ – Magnetic Interventional Ablation Catheter	See MDR 799863

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Cables	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2022-04-19	3209039	Issued
2022-07-06	3696362	Supplemented – Addition of TMA devices.
2022-09-12	3662389	Supplemented – Addition of CERABLATE® easy / easy TC devices. Amended – Addition of OSYPKA s.r.o subcontractor
2023-02-24	3836039	Supplemented – Addition of cables
2024-05-30	30048220	Supplemented – Addition of VACS II/III Gen 2 - percutaneous transluminal valvuloplasty catheters
Current	30274423	Supplemented – Addition of MAGiC™ – Magnetic Interventional Ablation Catheter. Amended – Alignment of device table header with certificate template.

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