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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Supplementary Information to CE 598775

Issued To:

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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

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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

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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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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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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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

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Date: **2021-05-06**
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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.

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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.