bsi.

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, endovascular grasping and snare/loop-catheters, TMA 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 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2016-07-22** Date: **2018-12-17** Expiry Date: **2023-12-18**

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