

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003 & EN ISO 13485:2012

This is to certify that:

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

Holds Certificate Number: MD 613632

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 & EN ISO 13485:2012 for the following scope:

Design, development, manufacturing, assembling and maintenance of medical devices for temporary stimulation and electrophysiology, permanent stimulation, HF-Ablation, interventional cardiology, medical components for the cardiac sector, neurology and contract sterilization services for medical devices in accordance with EN ISO 11135:2014.

Design, Entwicklung, Produktion, Montage und Wartung von Medizinprodukten aus den Bereichen Temporäre Stimulation und Elektrophysiologie, Permanente Stimulation, HF-Ablation, Interventionelle Kardiologie, Medical Components für den kardialen Bereich, Neurologie und Lohnsterilisation von Medizinprodukten nach EN ISO 11135:2014 als Dienstleistung



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2016-06-30

Effective Date: 2018-03-11

Latest Revision Date: 2018-03-08

Expiry Date: 2019-02-28



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Location	Registered Activities
Osypka AG Earl-H.-Wood-Straße 1 Rheinfelden 79618 Germany	<p>Design, development, manufacturing, assembling and maintenance of medical devices for temporary stimulation and electrophysiology, permanent stimulation, HF-Ablation, interventional cardiology, medical components for the cardiac sector, neurology and contract sterilization services for medical devices in accordance with EN ISO 11135:2014.</p> <p>Design, Entwicklung, Produktion, Montage und Wartung von Medizinprodukten aus den Bereichen Temporäre Stimulation und Elektrophysiologie, Permanente Stimulation, HF-Ablation, Interventionelle Kardiologie, Medical Components für den kardialen Bereich, Neurologie und Lohnsterilisation von Medizinprodukten nach EN ISO 11135:2014 als Dienstleistung</p>
Osypka AG Gottlieb-Daimler-Str. 5 Rheinfelden 79618 Germany	<p>Design, development, manufacturing, assembling and maintenance of medical devices for temporary stimulation and electrophysiology, permanent stimulation, HF-Ablation, interventional cardiology, medical components for the cardiac sector, neurology and contract sterilization services for medical devices in accordance with EN ISO 11135:2014.</p> <p>Design, Entwicklung, Produktion, Montage und Wartung von Medizinprodukten aus den Bereichen Temporäre Stimulation und Elektrophysiologie, Permanente Stimulation, HF-Ablation, Interventionelle Kardiologie, Medical Components für den kardialen Bereich, Neurologie und Lohnsterilisation von Medizinprodukten nach EN ISO 11135:2014 als Dienstleistung</p>

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