

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Osyka 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 13485:2016 & EN ISO 13485:2016 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, neurology and contract sterilization services in accordance with EN ISO 11135:2014+A1:2019.

Design, Entwicklung, Produktion, Montage und Wartung von Medizinprodukten aus den Bereichen Temporäre Stimulation und Elektrophysiologie, Permanente Stimulation, HF-Ablation, Interventionelle Kardiologie, Medical Components, Neurologie und Lohnsterilisation von Medizinprodukten nach EN ISO 11135:2014+A1:2019 als Dienstleistung.

For and on behalf of BSI:


Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2016-06-30

Latest Revision Date: 2024-02-27

Effective Date: 2024-03-11

Expiry Date: 2027-03-10

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Location	Registered Activities
Osypka AG Earl-H.-Wood-Straße 1 Rheinfelden 79618 Germany	Design, development, manufacturing, assembling and maintenance of medical devices for temporary stimulation and electrophysiology, permanent stimulation, HF-Ablation, interventional cardiology, medical components, neurology and contract sterilization services in accordance with EN ISO 11135:2014+A1:2019. Design, Entwicklung, Produktion, Montage und Wartung von Medizinprodukten aus den Bereichen Temporäre Stimulation und Elektrophysiologie, Permanente Stimulation, HF-Ablation, Interventionelle Kardiologie, Medical Components, Neurologie und Lohnsterilisation von Medizinprodukten nach EN ISO 11135:2014+A1:2019 als Dienstleistung.
Osypka AG Gottlieb-Daimler-Str. 5 Rheinfelden 79618 Germany	Design, development, manufacturing, assembling and maintenance of medical devices for temporary stimulation and electrophysiology, permanent stimulation, HF-Ablation, interventional cardiology, medical components, neurology and contract sterilization services in accordance with EN ISO 11135:2014+A1:2019. Design, Entwicklung, Produktion, Montage und Wartung von Medizinprodukten aus den Bereichen Temporäre Stimulation und Elektrophysiologie, Permanente Stimulation, HF-Ablation, Interventionelle Kardiologie, Medical Components, Neurologie und Lohnsterilisation von Medizinprodukten nach EN ISO 11135:2014+A1:2019 als Dienstleistung.
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