

Certificate of Registration

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

This is to certify that:

URSATEC GmbH
Marpinger Weg 4
66636 Tholey
Germany

Holds Certificate Number:

MD 598886

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, manufacture and distribution of sterile and non-sterile primary packaging materials and liquid, semi-solid and powdered Medical Devices with application system.

Design, Entwicklung, Herstellung und Vertrieb von sterilen und nicht-sterilen Primärpackmitteln und flüssigen, halbfesten und pulverförmigen Medizinprodukten mit Applikationssystem.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2016-05-27

Latest Revision Date: 2020-07-27

Effective Date: 2020-07-30

Expiry Date: 2023-07-29

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