

Certificate of Registration

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

This is to certify that:

NEXTEC medical GmbH
Zöllinplatz 4
79410 Badenweiler
Germany

Holds Certificate Number:

MD 730919

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 and distribution of non-active enema device for drug delivery.

Design, development, production and distribution of medical device software including Artificial Intelligence (AI).

Design, development, manufacturing and distribution of a substance based medical device for the treatment of dermatitis.

Provision of EU Representative services.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-10-29

Latest Revision Date: 2024-04-23

Effective Date: 2023-10-29

Expiry Date: 2026-10-28

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