

Certificate of Registration

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

This is to certify that:

Medical Enterprises Europe B.V.

Amsterdamseweg 147A
Amstelveen
1182 GT
The Netherlands

Holds Certificate Number:

MD 687160

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, manufacture, distribution, Service and installation of microwave therapy devices and related sterile disposable sets for the treatment of hyperthermia in combination with chemotherapeutic agent instillation.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2019-01-17

Latest Revision Date: 2025-01-14

Effective Date: 2025-01-17

Expiry Date: 2028-01-16

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Certificate No: MD 687160

Location

Medical Enterprises Europe B.V.
Amsterdamseweg 147A
Amstelveen
1182 GT
The Netherlands

MEL Medical Enterprises Ltd
6 Odem Street
Petah Tikva
4951789
Israel

Registered Activities

Head office with sales, marketing and incoming inspection and release for microwave therapy devices and related disposable sterile sets for hyperthermia and installation of chemotherapeutic agent

Design, manufacture, distribution, Service and installation of microwave therapy devices and related sterile disposable sets for the treatment of hyperthermia in combination with chemotherapeutic agent instillation.



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Printed copies can be validated at www.bsigroup.com/ClientDirectory

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