



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, and sales of microwave therapy devices and related disposable sterile sets for hyperthermia and instillation of chemotherapeutic agent.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2019-01-17 Latest Revision Date: 2019-01-17

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Effective Date: 2019-01-17

Expiry Date: 2022-01-16

...making excellence a habit."





This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated <u>online</u>. Printed copies can be validated at www.bsigroup.com/ClientDirectory

Certificate No: MD 687160

Location Registered Activities

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

Design, manufacture, and sales of microwave therapy devices and related disposable sterile sets for hyperthermia and instillation of chemotherapeutic agent.

MEL Medical Enterprises Ltd 6 Odem Street Petah Tikva 4951789 Israel Design, manufacture, and sales of microwave therapy devices and related disposable sterile sets for hyperthermia and instillation of chemotherapeutic agent.



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