

Certificate of Registration

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

This is to certify that:

Mölnlycke Manufacturing US, LLC
11 Twin Rivers Drive
Wiscasset
Maine
04578
USA

Holds Certificate Number:

MD 666825

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

The manufacture of foam with and without additives for incorporation into medical devices, sterile porcine collagen wound care dressing and non-sterile tubular support bandages.
The manufacture, service and repair of reusable mesher medical devices.



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2017-02-23

Latest Revision Date: 2019-03-21

Effective Date: 2018-11-28

Expiry Date: 2021-11-27

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