



By Royal Charter

Certificate of Registration

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

This is to certify that:

Mölnlycke Health Care AB
Box 13080
Gamlestadsvägen 3C
SE-402 52 Göteborg
Sweden

Holds Certificate Number:

MD 83345

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

The design, development, manufacture, marketing, sales and distribution of sterile wound and scar dressings, porcine collagen wound dressings, open wound products, cavity dressings, polyurethane foam with and without additives for incorporation into medical devices, swabs, sponges, sterile alcohol wipes, skin care products, non-sterile textile bandages and support, sterile wound irrigation solutions, operation sets, surgical and equipment drapes, procedure packs, surgical gowns and medical staff clothing for use in the patient environment, sterile and non-sterile medical gloves and sterile surgical gloves.

The design, development, manufacture, marketing, sales and distribution of single patient use Negative Pressure wound therapy pumps and accessories. Distribution of laparoscopic instruments.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2004-07-21

Effective Date: 2018-11-28

Latest Revision Date: 2018-11-26

Expiry Date: 2021-11-27



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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

Certificate No: **MD 83345**

Location

Registered Activities

Mölnlycke Health Care AB
Box 13080
Gamlestadvägen 3C
SE-402 52 Göteborg
Sweden

The design, development, manufacture, marketing, sales and distribution of sterile wound and scar dressings, porcine collagen wound dressings, open wound products, cavity dressings, polyurethane foam with and without additives for incorporation into medical devices, swabs, sponges, sterile alcohol wipes, skin care products, non-sterile textile bandages and support, sterile wound irrigation solutions, operation sets, surgical and equipment drapes, procedure packs, surgical gowns and medical staff clothing for use in the patient environment, sterile and non-sterile medical gloves and sterile surgical gloves.
The design, development, manufacture, marketing, sales and distribution of single patient use Negative Pressure wound therapy pumps and accessories. Distribution of laparoscopic instruments.

Molnlycke Health Care Pty Ltd
Level 4
12 Narabang Way
Belrose
New South Wales
2085
Australia

The provision of sales, marketing, and distribution of sterile wound and scar dressings, open wound products, cavity dressings, swabs, sponges, sterile alcohol wipes, skin care products, non-sterile textile bandages and supports, sterile irrigation solutions, operation sets, surgical and equipment drapes, procedure packs, surgical gowns and other medical staff clothing for use in the patient environment, sterile and non-sterile medical gloves and sterile surgical gloves and laparoscopic instruments.

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