



By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 722028 R000

Manufacturer: Mölnlycke Health Care AB

Address:

Gamlestadsvägen 3C
Box 13080
SE-402 52 Göteborg
Sweden

Single Registration Number: Not Available

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2020-05-08**

Date: **2021-05-03**

Expiry Date: **2025-05-07**

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Page 1 of 3

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Absorbent post-operative wound dressings	Class IIa
Transparent adhesive IV film dressings	Class Is
Surgical gowns	Class Is
Swabs and sponges	Class Is
Scar management dressings	Class Is
Surgical and equipment drapes	Class Is
Examination gloves	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile condition	

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference number	Action
08 May 2020	3110440	First Issue.
17 December 2021	3331670	Change to address of Siam Steri Services. Addition of Radiation (Gamma Sterilization) to activities for Siam Steri Services
22 April 2021	3406750	Amended - Addition of critical subcontractor STERIS TOMOE (Thailand) Ltd for Radiation (Gamma Sterilization) Amended - Removal of critical subcontractor Steris Applied Sterilisation Technologies, Swindon Amended - Addition of critical subcontractor Synergy Health Sterilisation UK Ltd, Bradford for Radiation (Gamma Sterilization)
Current	3426520	Supplemented – addition of device category: Absorbent post-operative wound dressings Amended – addition of Sterigenics Belgium (Petit-Rechain) SA for ETO Sterilization

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Page 3 of 3

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