By Royal Charter

# EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

## MDR 722506

**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 XI part A, the quality system meets the requirements of the Regulation.

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: **2020-04-22** Date: **2020-04-22** Expiry Date: **2025-04-21**

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### Device Schedule: Article 22.3 Systems and Procedure Pack

| Device(s) |
|---|
| Procedure Packs: |
| (1) Angiographic Trays |
| (2) Arthroscopic Trays |
| (3) Cardiothoracic Trays |
| (4) ENT Trays |
| (5) General Purpose Trays |
| (6) Neurosurgical Trays |
| (7) Obstetrical/Gynaecological Trays |
| (8) Ophthalmic Trays |
| (9) Orthopaedic Trays |
| (10) Urological Trays |
| (11) Dental Trays |
| (12) Laparoscopic Trays |
| (13) Anaesthesia Trays |
| (14) Haemodialysis Trays |
| For Systems and Procedure Packs under Article 22.3, the Notified Body conformity assessment is limited to the aspects relating to ensuring sterility until the sterile packaging is opened or damaged. |

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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 |
|---|---|---|
| Current | 3110440 | First Issue. |

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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.
A Member of the BSI Group of Companies.

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# List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

## MDR 722506

Date: **2020-04-22**

| Critical Subcontractor/Crucial Supplier | Service(s) supplied |
|---|---|
| Molnlycke Health Care Klinipro s.r.o<br>Na Novem Poli c.p. 382/1<br>Prumyslova zona Karvina<br>Karviná<br>Staré Mesto<br>733-01<br>Czech Republic | **Manufacture** |
| Mölnlycke Health Care ProcedurePak, s.r.o.<br>Šachetní 439/1<br>735 64 Havířov - Dolní Suchá<br>Czech Republic | **ETO Sterilization**<br>**Manufacture** |
| Sterigenics Belgium<br>(Petit- Rechain) SA<br>Zoning Industriel de Petit-Rechain<br>Avenue Andre Ernst 21<br>Verviers, Liege<br>B-4800<br>Belgium | **ETO Sterilization** |
| Sterigenics Germany GmbH<br>Kasteler Strasse 45<br>65203 Wiesbaden<br>Germany | **ETO Sterilization** |

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