

**Title:** Class I sterile, supplementaries to drapes

Page 1(2)

We, Mölnlycke Health Care AB, Gamlestadvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden being exclusively responsible manufacturer for conformity of the device/s; declare that the devices listed in the attached schedule are in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993, as amended by 2007/47/EEC, concerning medical devices, the Medical Devices Act SFS 1993:584 and the Swedish Medical Product Agency regulations and guidelines: Medical Devices, LVFS 2003:11, as amended by LVFS 2009:18.

Trade name/ Product name:	<b>Supplementaries to drapes</b>
------------------------------	----------------------------------

Product classification: **IS**  
Sterility Status: **Sterile**  
Measuring function: **No**

This declaration is supported by a conformity assessment procedure in accordance with	
Annex/es:	<b>V, VII</b>

Certificate number:	<b>CE 01966</b>
Issued by:	<b>BSI (2797)</b>
For non sterile, non-measuring Class I products, no certificate is issued by a Notified Body.	

Mölnlycke Health Care issues this declaration in recognition of all applicable harmonised standards.

Signed for and on behalf of Mölnlycke Health AB Care

Date: **2021-03-03**      Function: **Regulatory Affairs Manager  
Compliance**

Name: **Karin Darle Olsson**

Signature:



**Product(s) covered by this declaration:**

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
705860	INSTRUMENT BAG	58967 Instrument management bag, sterile
8000004	HAND TOWEL	45171 Dry medical towel/wipe
80003113	TUBE POCKET	47783 Patient surgical drape, single-use, sterile
84357150	ABSORBENT TOWEL	14077 Surgical towel
84357160	ABSORBENT TOWEL	14077 Surgical towel
84541230	DISLOCATION BAG	47783 Patient surgical drape, single-use, sterile
84541251	BABY BLANKET	58933 Infant blanket, single-use, sterile