

**Title:** Sterile, patient drapes

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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>Patient drapes</b>
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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</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.	

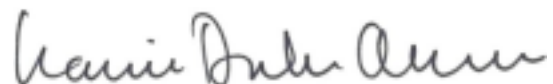
Mölnlycke Health Care issues this declaration in recognition of all applicable harmonised standards.

Signed for and on behalf of M ö Inlycke Health Care

Date: **2020-12-14**      Function: **Regulatory Affairs Manager  
Compliance**

Name: **Karin Darle Olsson**

Signature:





## Declaration of Conformity EU

Document ID: PD-577006 Rev: 04  
Created by: Gayle Wood  
Approved by: Karin Darle Olsson  
Approval date: 2020-12-14

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**Document template:** Declaration of Conformity EU Rev: 05

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

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
801526	INCISE DRAPE	47783 Patient surgical drape, single-use, sterile
803026	INCISE DRAPE	47783 Patient surgical drape, single-use, sterile
804040	INCISE DRAPE	47783 Patient surgical drape, single-use, sterile
804555	INCISE DRAPE	47783 Patient surgical drape, single-use, sterile
805680	INCISE DRAPE	47783 Patient surgical drape, single-use, sterile
80649015	OP-SHEET	47783 Patient surgical drape, single-use, sterile
935569	ADHESIVE APERTURE DRAPE	47783 Patient surgical drape, single-use, sterile