



Document ID: Created by: Approved by: Approval date:

PD-534697 Rev: 01 Zahrah Chaudhary Karin Darle Olsson 2019-10-04

Title: Arm sleeve, sterile Page 1(2)

We, Mölnlycke Health Care AB, Gamlestadsvägen 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/ Arm sleeve, sterile Product name:

Product classification: IS

Sterility Status: **Sterile** 

Measuring function: No

This declaration is supported by a conformity assessment procedure in accordance with

V, VII Annex/es:

Certificate number: **CE 01966** 

Issued by: **BSI (2797)** 

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 Care

Function: Date: 2019-10-04 Regulatory Affairs Manager

Compliance

Canie Inle Our Name: Karin Darle Olsson Signature:

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## Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
623501		35091 Operating room gown, single-use