



Document ID: Created by: Approved by: Approval date: PD-545349 Rev: 00 Zahrah Chaudhary Karin Darle Olsson 2018-06-14

**Title:** Barrier Protective Aprons

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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/ Product name:	Protective Aprons, non-sterile
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Product classification:

Sterility Status: Non-sterile

Measuring function: No

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

Annex/es: VII

Certificate number: Not Applicable

Issued by: Not Applicable

For non sterile, non-measuring Class I products, no certificate is issued by a Notified Body.

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

Signed for and on behalf of Mölnlycke Health Care

Date: 2018-06-14 Function: Regulatory Affairs Manager

Compliance

Name: Karin Darle Olsson Signature:



Title: Barrier Protective Aprons

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## Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
613000	PROTECTIVE APRON	40511
613100	PROTECTIVE APRON	40511

Document template: Declaration of Conformity EU Rev: 05