Declaration of Conformity EU



Document ID: Created by: Approved by: Approval date: PD-504999 Rev: 06 Sofia Horkeby Karin Darle Olsson 2020-09-03

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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:

Mesorb

Product classification: IIb

Sterility Status: Sterile

Measuring function: No

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

Annex/es:

Certificate number: CE 01965

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 M ö Inlycke Health Care

Date: 2020-09-03 Function: Regulatory Affairs Manager

Compliance

Name: Karin Darle Olsson Signature:



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Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
677001	Absorbent dressing	48131 Non-woven gauze pad, sterile
677080	Absorbent dressing	48131 Non-woven gauze pad, sterile
677201	Absorbent dressing	48131 Non-woven gauze pad, sterile
677280	Absorbent dressing	48131 Non-woven gauze pad, sterile
677401	Absorbent dressing	48131 Non-woven gauze pad, sterile
677480	Absorbent dressing	48131 Non-woven gauze pad, sterile
677601	Absorbent dressing	48131 Non-woven gauze pad, sterile
677680	Absorbent dressing	48131 Non-woven gauze pad, sterile
677701	Absorbent dressing	48131 Non-woven gauze pad, sterile
677780	Absorbent dressing	48131 Non-woven
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677801	Absorbent dressing	48131 Non-woven gauze pad, sterile
677880	Absorbent dressing	48131 Non-woven gauze pad, sterile