Declaration of Conformity EU



Document ID: Created by: Approved by: Approval date: PD-384754 Rev: 18 Zahrah Chaudhary Karin Darle Olsson 2020-06-30

Title: Medical Face Masks

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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:

Medical Face Masks

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.

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: 2020-06-30 Function: Regulatory Affairs Manager

Compliance

Name: Karin Darle Olsson Signature:

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Declaration of Conformity EU

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Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
106332	MEDICAL FACE MASK	35177 Surgical face mask, single-use
4224	MEDICAL FACE MASK	35177 Surgical face mask, single-use
42270	MEDICAL FACE MASK	35177 Surgical face mask, single-use
42280	MEDICAL FACE MASK	35177 Surgical face mask, single-use
4228	MEDICAL FACE MASK	35177 Surgical face mask, single-use
42290	MEDICAL FACE MASK	35177 Surgical face mask, single-use
4229	MEDICAL FACE MASK	35177 Surgical face mask, single-use
4230	MEDICAL FACE MASK	35177 Surgical face mask, single-use
4231	MEDICAL FACE MASK	35177 Surgical face mask, single-use
4232 Document template: Declaration of	MEDICAL FACE MASK f Conformity EU Rev: 05	35177 Surgical face mask, single-use
4234	MEDICAL FACE MASK	35177 Surgical face mask, single-use
4236	MEDICAL FACE MASK	35177 Surgical face mask, single-use
4237	MEDICAL FACE MASK	35177 Surgical face mask, single-use







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Product Reference:	Product Descriptor:	GMDN Code:
4238	MEDICAL FACE MASK	35177 Surgical face mask, single-use
4239	MEDICAL FACE MASK	35177 Surgical face mask, single-use
4267	MEDICAL FACE MASK	35177 Surgical face mask, single-use
428801	MEDICAL FACE MASK	35177 Surgical face mask, single-use
428901	MEDICAL FACE MASK	35177 Surgical face mask, single-use
4291	MEDICAL FACE MASK	35177 Surgical face mask, single-use
4301	MEDICAL FACE MASK	35177 Surgical face mask, single-use
4302	MEDICAL FACE MASK	35177 Surgical face mask, single-use
4311	MEDICAL FACE MASK	35177 Surgical face mask, single-use
4312	MEDICAL FACE MASK	35177 Surgical face mask, single-use
4313	MEDICAL FACE MASK	35177 Surgical face mask, single-use
D4ஆ்ஷ்கோt template: Declaration (OF PMEDI©ALRFA©E MASK	35177 Surgical face mask, single-use
4330	MEDICAL FACE MASK	35177 Surgical face mask, single-use
4334	MEDICAL FACE MASK	35177 Surgical face mask, single-use



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Product Reference:	Product Descriptor:	GMDN Code:
657000	MEDICAL FACE MASK	35177 Surgical face mask, single-use
657010	MEDICAL FACE MASK	35177 Surgical face mask, single-use
657030	MEDICAL FACE MASK	35177 Surgical face mask, single-use
657060	MEDICAL FACE MASK	35177 Surgical face mask, single-use
657070	SMEDICAL FACE MASK	35177 Surgical face mask, single-use
657100	MEDICAL FACE MASK	35177 Surgical face mask, single-use
657200	MEDICAL FACE MASK	35177 Surgical face mask, single-use
658000	MEDICAL FACE MASK	35177 Surgical face mask, single-use
658010	MEDICAL FACE MASK	35177 Surgical face mask, single-use
658030	MEDICAL FACE MASK	35177 Surgical face mask, single-use
658200	MEDICAL FACE MASK	35177 Surgical face mask, single-use
Deggeonemplate: Declaration of	ͶMEDI©ALRFA©E MASK	35177 Surgical face mask, single-use
658391	MEDICAL FACE MASK	35177 Surgical face mask, single-use