

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>Headwear</b>
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Product classification: **I**  
Sterility Status: **Non-sterile**  
Measuring function: **No**

This declaration is supported by a conformity assessment procedure in accordance with	
Annex/es:	<b>VII</b>

Certificate number:	<b>Not Applicable</b>
Issued by:	<b>Not Applicable</b>
For non sterile, non-measuring Class I products, no certificate is issued by a Notified Body.	

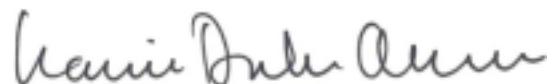
Mölnlycke Health Care issues this declaration in recognition of all applicable harmonised standards.

Signed for and on behalf of Mölnlycke Health Care

Date: **2020-05-27**      Function: **Regulatory Affairs Manager  
Compliance**

Name: **Karin Darle Olsson**

Signature:





## Declaration of Conformity EU

Document ID: PD-393192 Rev: 13  
Created by: Zahrah Chaudhary  
Approved by: Karin Darle Olsson  
Approval date: 2020-05-27

**Title:** Headwear

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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>
42013	NURSES CAP	32297 Surgical cap, single-use
42021	SURGICAL CAP	32297 Surgical cap, single-use
42022	SURGICAL CAP	32297 Surgical cap, single-use
42023	SURGICAL CAP	32297 Surgical cap, single-use
42024	SURGICAL CAP	32297 Surgical cap, single-use
42025	SURGICAL CAP	32297 Surgical cap, single-use
42033	SURGICAL CAP	32297 Surgical cap, single-use
42034	SURGICAL CAP	32297 Surgical cap, single-use
42036	SURGICAL CAP	32297 Surgical cap, single-use
42042	SURGICAL CAP	32297 Surgical cap, single-use
<b>Document template:</b> Declaration of Conformity EU Rev: 05		
42044	SURGICAL CAP	32297 Surgical cap, single-use
42062	SURGICAL CAP	32297 Surgical cap, single-use
42063	SURGICAL CAP	32297 Surgical cap, single-use

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
42071	SURGICAL HOOD	32297 Surgical cap, single-use
42072	SURGICAL HOOD	32297 Surgical cap, single-use
42073	SURGICAL HOOD	32297 Surgical cap, single-use
42074	SURGICAL HOOD WITH SWEATBAND	32297 Surgical cap, single-use
42076	SURGICAL HOOD WITH SWEATBAND	32297 Surgical cap, single-use
42093	SURGICAL CAP	32297 Surgical cap, single-use
42094	SURGICAL CAP	32297 Surgical cap, single-use
42112	NURSES CAP	32297 Surgical cap, single-use
42113	NURSES CAP	32297 Surgical cap, single-use
42610	NURSES CAP	32297 Surgical cap, single-use
42620	NURSES CAP	32297 Surgical cap, single-use
42630	NURSES CAP	32297 Surgical cap, single-use
620100	SURGICAL HOOD	32297 Surgical cap, single-use
620105	SURGICAL HOOD	32297 Surgical cap, single-use

D:\2020 template: Declaration of Conformity Rev 15

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
620200	SURGICAL HOOD	32297 Surgical cap, single-use
620205	SURGICAL HOOD	32297 Surgical cap, single-use
620250	SURGICAL HOOD	32297 Surgical cap, single-use
620300	SURGICAL CAP	32297 Surgical cap, single-use
620500	SURGICAL CAP	32297 Surgical cap, single-use
620800	SURGICAL CAP	32297 Surgical cap, single-use
620810	SURGICAL CAP	32297 Surgical cap, single-use
620900	NURSES CAP	32297 Surgical cap, single-use
620910	NURSES CAP	32297 Surgical cap, single-use
620920	NURSES CAP	32297 Surgical cap, single-use
621000	SURGICAL CAP	32297 Surgical cap, single-use
621001	SURGICAL CAP	32297 Surgical cap, single-use
621005	SURGICAL CAP	32297 Surgical cap, single-use
621010	SURGICAL CAP	32297 Surgical cap, single-use

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
621020	SURGICAL CAP	32297 Surgical cap, single-use
621301	SURGICAL CAP	32297 Surgical cap, single-use
621500	NURSES CAP	32297 Surgical cap, single-use
621600	SURGICAL CAP	32297 Surgical cap, single-use
621700	SURGICAL CAP	32297 Surgical cap, single-use
621715	NURSES CAP	32297 Surgical cap, single-use
621725	NURSES CAP	32297 Surgical cap, single-use
621735	NURSES CAP	32297 Surgical cap, single-use
621815	NURSES CAP	32297 Surgical cap, single-use
621825	NURSES CAP	32297 Surgical cap, single-use
621835	NURSES CAP	32297 Surgical cap, single-use
621845	NURSES CAP, SWEATBAND	32297 Surgical cap, single-use
621925	NURSES CAP	32297 Surgical cap, single-use
622010	SURGICAL CAP, SWEATBAND	32297 Surgical cap, single-use



Title: Headwear

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<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
70000002	SURGICAL HOOD	32297 Surgical cap, single-use
70042013	NURSES CAP	32297 Surgical cap, single-use