



# EU Declaration of Conformity according to MDR

Document ID: PD-608121 Rev: 01  
Created by: Zahrah Chaudhary  
Approved by: Christina Lewing  
Approval date: 2021-04-21

Title: Headwear

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We, Mölnlycke Health Care, 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 Medical Device Regulation 2017/745, concerning medical devices.

Other Union Legislation applicable: **Not applicable**

Trade name/ Product name:	<b>Headwear</b>
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Product classification: **I**  
MDR Classification Rule: **1**  
Sterility: **Non-sterile**  
Measuring function: **No**

This declaration is supported by a conformity assessment procedure in accordance with	
Annex/es:	<b>IV</b>
Common Specification:	<b>No CS is applicable</b>

Certificate number:	<b>Not Applicable</b>
Issued by:	<b>Not Applicable</b>
NB. 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 applied harmonised standards.

Signed for and on behalf of Mölnlycke Health Care AB

Place of Issue: Göteborg, Sweden

Date: **2021-04-21** Function: **Regulatory Affairs Director**

Name: **Christina Lewing**

Signature:

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Intended Purpose: The intended use of headwear is infection control by reducing the risk of transferring bacteria, hair or particles into the surgical wound

**Product(s) covered by this declaration:**

Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
42013	NURSES CAP	73324300000000207JY	32297 Surgical cap, single-use
42021	SURGICAL CAP	73324300000000207JY	32297 Surgical cap, single-use
42022	SURGICAL CAP	73324300000000207JY	32297 Surgical cap, single-use
42023	SURGICAL CAP	73324300000000207JY	32297 Surgical cap, single-use
42024	SURGICAL CAP	73324300000000207JY	32297 Surgical cap, single-use
42033	SURGICAL CAP	73324300000000207JY	32297 Surgical cap, single-use
42034	SURGICAL CAP	73324300000000207JY	32297 Surgical cap, single-use
42042	SURGICAL CAP	73324300000000207JY	32297 Surgical cap, single-use
42062	SURGICAL CAP	73324300000000207JY	32297 Surgical cap, single-use
42063	SURGICAL CAP	73324300000000207JY	32297 Surgical cap, single-use
42071	SURGICAL HOOD	73324300000000207JY	32297 Surgical cap, single-use
42072	SURGICAL HOOD	73324300000000207JY	32297 Surgical cap, single-use



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<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>Basic UDI-DI:</b>	<b>GMDN Code:</b>
42073	SURGICAL HOOD	73324300000000207JY	32297 Surgical cap, single-use
42074	SURGICAL HOOD WITH SWEATBAND	73324300000000207JY	32297 Surgical cap, single-use
42076	SURGICAL HOOD WITH SWEATBAND	73324300000000207JY	32297 Surgical cap, single-use
42093	SURGICAL CAP	73324300000000207JY	32297 Surgical cap, single-use
42113	NURSES CAP	73324300000000207JY	32297 Surgical cap, single-use
620100	SURGICAL HOOD	73324300000000207JY	32297 Surgical cap, single-use
620105	SURGICAL HOOD	73324300000000207JY	32297 Surgical cap, single-use
620200	SURGICAL HOOD	73324300000000207JY	32297 Surgical cap, single-use
620205	SURGICAL HOOD	73324300000000207JY	32297 Surgical cap, single-use
620250	SURGICAL HOOD	73324300000000207JY	32297 Surgical cap, single-use
620300	SURGICAL CAP	73324300000000207JY	32297 Surgical cap, single-use
620500	SURGICAL CAP	73324300000000207JY	32297 Surgical cap, single-use
620800	SURGICAL CAP	73324300000000207JY	32297 Surgical cap, single-use
620810	SURGICAL CAP	73324300000000207JY	32297 Surgical cap, single-use
620900	NURSES CAP	73324300000000207JY	32297 Surgical cap, single-use
621000	SURGICAL CAP	73324300000000207JY	32297 Surgical cap, single-use



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<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>Basic UDI-DI:</b>	<b>GMDN Code:</b>
621001	SURGICAL CAP	73324300000000207JY	32297 Surgical cap, single-use
621005	SURGICAL CAP	73324300000000207JY	32297 Surgical cap, single-use
621010	SURGICAL CAP	73324300000000207JY	32297 Surgical cap, single-use
621020	SURGICAL CAP	73324300000000207JY	32297 Surgical cap, single-use
621301	SURGICAL CAP	73324300000000207JY	32297 Surgical cap, single-use
621500	NURSES CAP	73324300000000207JY	32297 Surgical cap, single-use
621700	SURGICAL CAP	73324300000000207JY	32297 Surgical cap, single-use
621715	NURSES CAP	73324300000000207JY	32297 Surgical cap, single-use
621725	NURSES CAP	73324300000000207JY	32297 Surgical cap, single-use
621735	NURSES CAP	73324300000000207JY	32297 Surgical cap, single-use
621815	NURSES CAP	73324300000000207JY	32297 Surgical cap, single-use
621825	NURSES CAP	73324300000000207JY	32297 Surgical cap, single-use
621835	NURSES CAP	73324300000000207JY	32297 Surgical cap, single-use
621845	NURSES CAP, SWEATBAND	73324300000000207JY	32297 Surgical cap, single-use
621925	NURSES CAP	73324300000000207JY	32297 Surgical cap, single-use
622010	SURGICAL CAP, SWEATBAND	73324300000000207JY	32297 Surgical cap, single-use



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<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>Basic UDI-DI:</b>	<b>GMDN Code:</b>
70000002	SURGICAL HOOD	733243000000000207JY	32297 Surgical cap, single-use
70042013	NURSES CAP	733243000000000207JY	32297 Surgical cap, single-use

<b>Revision history</b>	
<b>Revision</b>	<b>Comment</b>
01	Dual sourcing of 42073, 42093, 620200 at Copious KH.