



EU Declaration of Conformity according to MDR

Document ID: PD-608121 Rev:02
Created by: Zahrah Chaudhary
State: Released
Approved by: Christina Lewing
Release date: 2022-03-01 15:26:24

Title: Headwear Surgical and Bouffant

Dates and times in Greenwich Mean Time, 24 hours format

We, Mölnlycke Health Care AB, Gamlestadvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden, SRN SE-MF-000014042, 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 Medical Device Regulation 2017/745, concerning medical devices.

Other Union Legislation applicable: Not applicable

Trade name / Product name:	Headwear
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Product Classification: MDR Class I ns
MDR Classification Rule: 1
Sterility: Non-sterile
Measuring Function: No

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

Certificate number:	Not Applicable	
Issued by:	Not Applicable	Id No:
	<i>(Notified Body Name)</i>	
<i>NB. For non-sterile, non-measuring Class I products, no certificate is issued by a Notified Body.</i>		

Mölnlycke Health Care AB issues this declaration in recognition of applied harmonized standards.

Signed for and on behalf of Mölnlycke Health Care AB

Place of Issue: Göteborg, Sweden

Date: 2022-03-01 Function: Global Regulatory Affairs Director

Name: Christina Lewing

Signature:



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Generic product information	
Intended Purpose:	The intended use of headwear is infection control by reducing the risk of transferring bacteria, hair or particles into the surgical wound
Basic UDI-DI:	733243000000000207JY
GMDN Code:	32297 Surgical cap, single-use

Product References Covered by this Declaration:	Product Descriptor:
42033	SURGICAL CAP
42034	SURGICAL CAP
42042	SURGICAL CAP
42062	SURGICAL CAP
42063	SURGICAL CAP
42071	SURGICAL HOOD
42072	SURGICAL HOOD
42073	SURGICAL HOOD
42074	SURGICAL HOOD WITH SWEATBAND
42076	SURGICAL HOOD WITH SWEATBAND
620100	SURGICAL HOOD
620105	SURGICAL HOOD
620200	SURGICAL HOOD
620205	SURGICAL HOOD
620250	SURGICAL HOOD
620300	SURGICAL CAP
620500	SURGICAL CAP
620800	SURGICAL CAP
620810	SURGICAL CAP
620900	NURSES CAP



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621000	SURGICAL CAP
621001	SURGICAL CAP
621005	SURGICAL CAP
621010	SURGICAL CAP
621020	SURGICAL CAP
621301	SURGICAL CAP
621500	NURSES CAP
621700	SURGICAL CAP
621715	NURSES CAP
621725	NURSES CAP
621735	NURSES CAP
621815	NURSES CAP
621825	NURSES CAP
621835	NURSES CAP
621845	NURSES CAP, SWEATBAND
621925	NURSES CAP
622010	SURGICAL CAP, SWEATBAND
70000002	SURGICAL HOOD
70042013	NURSES CAP