EU Declaration of Conformity according to MDR

Title: Headwear Surgical and Bouffant

We, Mölnlycke Health Care AB, Entreprenörsstråket 21, SE-431 53, Mölndal, 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

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:
	(Notified Body Name)	
NB. For non-sterile, non-measuring Class I products, no certificate is issued by a Notified Body.		

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: Mölndal, Sweden

Date: 2025-05-06 Function: Regulatory Affairs Excellence Director

Name: Karin Darle Olsson Signature:



Mölnlycke®

Title: Headwear Surgical and Bouffant

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
EMDN Code:	T0207 CAPS AND HEADWEAR (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT - PPE)

Product References Covered by this Declaration:	Product	Product Descriptor:
42033	CHIC Surgical Cap Green	SURGICAL CAP
42034	CHIC Surgical Cap Blue	SURGICAL CAP
42042	Theatre Cap, BLUE	SURGICAL CAP
42062	Elast Surgical Cap Blue	SURGICAL CAP
42063	Elast Surgical Cap Green	SURGICAL CAP
42071	All Surgical Hood Green	SURGICAL HOOD
42072	Surgeons hood, ALL, Blue	SURGICAL HOOD
42073	Surgical Hood. ALL Green	SURGICAL HOOD
42074	All Pro Surgical Hood w Sweatband	SURGICAL HOOD WITH SWEATBAND
42076	All Pro Surgical Hood w Sweatband	SURGICAL HOOD WITH SWEATBAND
620100	Cap Tuck Surgeons Hood	SURGICAL HOOD
620105	CAP TUCK BLUE	SURGICAL HOOD
620200	CAP GLENN	SURGICAL HOOD
620205	CAP GLENN, Blue	SURGICAL HOOD
620250	CAP ALBIN	SURGICAL HOOD
620300	Cap Jack	SURGICAL CAP
620500	CAP FLORY	SURGICAL CAP

620800	EUROCAP BLUE	SURGICAL CAP
620810	EUROCAP GREEN	SURGICAL CAP
620900	Cap Charlotte White	NURSES CAP
621000	CAP KOSACK GREEN	SURGICAL CAP
621001	CAP KOSACK VIOLET	SURGICAL CAP
621005	CAP KOSACK BLUE	SURGICAL CAP
621010	CAP, KOSACK C GREEN	SURGICAL CAP
621020	Cap Kosack C blue	SURGICAL CAP
621301	CAP PHILIP	SURGICAL CAP
621500	ANNIE MIXED COLOURS 55CM	NURSES CAP
621700	Cap Peggy Green	SURGICAL CAP
621715	CAP ANNIE BLUE 50CM	NURSES CAP
621725	CAP ANNIE GREEN 50CM	NURSES CAP
621735	CAP ANNIE WHITE 50CM	NURSES CAP
621815	Cap Annie Blue L	NURSES CAP
621825	Cap Annie Green L	NURSES CAP
621835	MOB CAP ANNIE WHITE 55 CM	NURSES CAP
621845	Mob Cap Annie Pro, Green; L	NURSES CAP, SWEATBAND
621925	CAP ANNIE GREEN, 60CM	NURSES CAP
622010	Cap Commodus	SURGICAL CAP, SWEATBAND
70042013	SURGINE FLOTT, latex free	NURSES CAP