

We, Mölnlycke Health Care AB, Gamlestadvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden being the manufacturer of the following, 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:	BARRIER® CAPS
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Product classification: **I**Sterility: **Non-sterile**Measuring function: **No**

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

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

Signed for and on behalf of Mölnlycke®

Date: **2012-11-26**Function: **Director of Regulatory Affairs**Name: **Mike Edwards**

Signature:



Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
42007	FUNNY SURGEONS HOOD WITH EARS	32297
42021	SURGICAL CAP	32297
42022	SURGICAL CAP	32297
42023	SURGICAL CAP	32297
42024	SURGICAL CAP	32297
42025	SURGICAL CAP	32297
42031	SURGICAL CAP	32297
42033	SURGICAL CAP	32297
42034	SURGICAL CAP	32297
42035	SURGICAL CAP	32297
42036	SURGICAL CAP	32297
42042	SURGICAL CAP	32297
42044	SURGICAL CAP	32297
42061	SURGICAL CAP	32297
42062	SURGICAL CAP	32297
42063	SURGICAL CAP	32297
42071	SURGICAL HOOD	32297
42072	ALL, SURGEONS HOOD	32297
42073	ALL, SURGEONS HOOD	32297
42074	SURGICAL HOOD WITH SWEATBAND	32297
42076	SURGICAL HOOD WITH SWEATBAND	32297
42094	SURGICAL CAP	32297
42112	NURSES CAP	32297
620100	Surgeons Hood, Green	32297

Product Reference:	Product Descriptor:	GMDN Code:
620105	Surgeons Hood, Blue	32297
620200	Surgeons Hood with shoulder cover and sweatband	32297
620205	Surgeons Hood with shoulder cover and sweatband	32297
620250	Surgeons Hood with collar and sweatband	32297
620300	SURGICAL CAP	32297
620500	SURGICAL CAP	32297
621000	SURGICAL CAP	32297
621001	SURGICAL CAP	32297
621005	SURGICAL CAP	32297
621010	SURGICAL CAP	32297
621020	SURGICAL CAP	32297
621301	SURGICAL CAP	32297
621500	NURSES CAP	32297
621600	SURGICAL CAP	32297
621700	SURGICAL CAP	32297
621715	NURSES CAP	32297
621725	NURSES CAP	32297
621735	NURSES CAP	32297
621815	NURSES CAP	32297
621825	NURSES CAP	32297
621835	NURSES CAP	32297
621845	NURSES CAP, SWEATBAND	32297
621925	NURSES CAP	32297
622000	SURGICAL CAP	32297

Title: Class 1 non sterile caps

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Product Reference:	Product Descriptor:	GMDN Code:
622010	SURGICAL CAP, SWEATBAND	32297
622030	SURGICAL CAP	32297
70000002	SURGICAL HOOD	32297