

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:	Supplementary to drapes
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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 Health Care issues this declaration in recognition of all applicable harmonised standards.

Signed for and on behalf of Mölnlycke Health Care

Date: **2014-03-07** Function: **RA Director Operations**

Name: **Anders Edner** Signature:



Title: Class I Non-sterile, supplementaries to drapes

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Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
304998	ABSORBENT TOWEL	35531
748140	CELLULOSE TOWEL	
815310	IRRIGATION POUCH	
815320	INSTRUMENT BAG	58967
8183	TUBE POCKET	35531
824098	TUBE HOLDER	59024
904762	TUBE HOLDER	59024
910433	BABY BLANKET	58934
911500	OP-TAPE	58986
923720	ABSORBENT TOWEL	14077
9318	OPHTHALMIC DRAINAGE POUCH	58982
947445	DEFIBRILLATOR BAG	
9534	BABY BLANKET	58934
9547	CELLULOSE TOWEL	35531
975880	INSTRUMENT BAG	58968
976035	FLUID COLLECTION POUCH	58982
977035	SUCTION AND DIATHERMY BAG	
9901	IRRIGATION POUCH	58982
9931	ABSORBENT TOWEL	14077