We, Mölnlycke Health Care AB, Gamlestadsvägen 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 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:	**Mefix**

Product classification:	**I**
Sterility Status:	**Non-sterile**
Measuring function:	**No**

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

Certificate number:	**Not Applicable**
Issued by:	**Not Applicable**
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 all applicable harmonised standards.

Signed for and on behalf of Mölnlycke Health Care

Date: **2019-09-19** Function: **Regulatory Affairs Manager Compliance**

Name: **Karin Darle Olsson** Signature:



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Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
310250	Self-adhesive fabric	16866 Basic adhesive tape
310276	Self-adhesive fabric	16866 Basic adhesive tape
310299	Self-adhesive fabric	16866 Basic adhesive tape
310500	Self-adhesive fabric	16866 Basic adhesive tape
310540	Self-adhesive fabric	16866 Basic adhesive tape
310570	Self-adhesive fabric	16866 Basic adhesive tape
310576	Self-adhesive fabric	16866 Basic adhesive tape
310580	Self-adhesive fabric	16866 Basic adhesive tape
310584	Self-adhesive fabric	16866 Basic adhesive tape
310586	Self-adhesive fabric	16866 Basic adhesive tape
310599	Self-adhesive fabric	16866 Basic adhesive tape
311000	Self-adhesive fabric	16866 Basic adhesive tape
311040	Self-adhesive fabric	16866 Basic adhesive tape
311070	Self-adhesive fabric	16866 Basic adhesive tape

Product Reference:	Product Descriptor:	GMDN Code:
311076	Self-adhesive fabric	16866 Basic adhesive tape
311080	Self-adhesive fabric	16866 Basic adhesive tape
311084	Self-adhesive fabric	16866 Basic adhesive tape
311086	Self-adhesive fabric	16866 Basic adhesive tape
311090	Self-adhesive fabric	16866 Basic adhesive tape
311099	Self-adhesive fabric	16866 Basic adhesive tape
311500	Self-adhesive fabric	16866 Basic adhesive tape
311570	Self-adhesive fabric	16866 Basic adhesive tape
311576	Self-adhesive fabric	16866 Basic adhesive tape
311580	Self-adhesive fabric	16866 Basic adhesive tape
311586	Self-adhesive fabric	16866 Basic adhesive tape
311590	Self-adhesive fabric	16866 Basic adhesive tape
311599	Self-adhesive fabric	16866 Basic adhesive tape
312000	Self-adhesive fabric	16866 Basic adhesive tape
312076	Self-adhesive fabric	16866 Basic adhesive tape

Product Reference:	Product Descriptor:	GMDN Code:
313000	Self-adhesive fabric	16866 Basic adhesive tape
313076	Self-adhesive fabric	16866 Basic adhesive tape