

We, Mölnlycke Health Care AB, Gamlestadvägen 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: | Mepilex Border Post-Op/Mepilex Surgical |
|------------------------------|--|

Product classification: **IIa**Sterility Status: **Sterile**Measuring function: **No**

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

Certificate number: **CE 01965**Issued by: **BSI (2797)**

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: **2019-06-27**Function: **Regulatory Affairs Manager
Compliance**Name: **Karin Darle Olsson**

Signature:



Product(s) covered by this declaration:

| Product Reference: | Product Descriptor: | GMDN Code: |
|---------------------------|---|------------------------|
| 496100 | Self-adherent soft silicone surgical dressing | 34864 Adhesive bandage |
| 496200 | Self-adherent soft silicone surgical dressing | 34864 Adhesive bandage |
| 496300 | Self-adherent soft silicone surgical dressing | 34864 Adhesive bandage |
| 496400 | Self-adherent soft silicone surgical dressing | 34864 Adhesive bandage |
| 496405 | Self-adherent soft silicone surgical dressing | 34864 Adhesive bandage |
| 496450 | Self-adherent soft silicone surgical dressing | 34864 Adhesive bandage |
| 496455 | Self-adherent soft silicone surgical dressing | 34864 Adhesive bandage |
| 496600 | Self-adherent soft silicone surgical dressing | 34864 Adhesive bandage |
| 496605 | Self-adherent soft silicone surgical dressing | 34864 Adhesive bandage |
| 496650 | Self-adherent soft silicone surgical dressing | 34864 Adhesive bandage |
| 499400 | Self-adherent soft silicone surgical dressing | 34864 Adhesive bandage |
| 499450 | Self-adherent soft silicone surgical dressing | 34864 Adhesive bandage |
| 499600 | Self-adherent soft silicone surgical dressing | 34864 Adhesive bandage |
| 499650 | Self-adherent soft silicone surgical dressing | 34864 Adhesive bandage |