

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:	Alldress
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Product classification: **IIb**

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 AB Care

Date: **2020-11-06**

Function:

**Regulatory Affairs Manager
Compliance**

Name: **Karin Darle Olsson**

Signature:



Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
265320	Absorbent vapour-permeable adhesive film dressing	44970 Exudate - absorbent dressing, non-gel
265329	Absorbent vapour-permeable adhesive film dressing	44970 Exudate - absorbent dressing, non-gel
265340	Absorbent vapour-permeable adhesive film dressing	44970 Exudate - absorbent dressing, non-gel
265349	Absorbent vapour-permeable adhesive film dressing	44970 Exudate - absorbent dressing, non-gel
265360	Absorbent vapour-permeable adhesive film dressing	44970 Exudate - absorbent dressing, non-gel
265369	Absorbent vapour-permeable adhesive film dressing	44970 Exudate - absorbent dressing, non-gel