

Declaration of Conformity EU

Document ID: Created by: Approved by: Approval date:

Title: Mesalt

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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:	Mesalt		
Product classification:	111		
Sterility Status:	Sterile		
Measuring function:	Νο		
This declaration is supported by a conformity assessment procedure in accordance with			
Annex/es:	II		
Certificate number:	CE 01965;CE 610149		
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: 2021-04-12

Function:

Regulatory Affairs Manager Compliance

Name:

Karin Darle Olsson

Signature:

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Title: Mesalt

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Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
285280	Cleansing Dressing with Sodium Chloride	58475 Sodium chloride dressing
285580	Cleansing Dressing with Sodium Chloride	58475 Sodium chloride dressing
285780	Cleansing Dressing with Sodium Chloride	58475 Sodium chloride dressing
286080	Cleansing Dressing with Sodium Chloride	58475 Sodium chloride dressing