



# EU Declaration of Conformity according to MDR

Document ID: PD-600246 Rev:00  
 Created by: Pia Malmberg  
 State: Released  
 Approved by: Christina Lewing  
 Approval date: 2022-12-20 12:34:37  
 Release date: 2022-12-20 12:34:42

Title: Mesalt

Dates and times in Greenwich Mean Time, 24 hours format

We, Mölnlycke Health Care AB, Gamlestadvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden, SRN SE-MF-000014042, 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 Medical Device Regulation 2017/745, concerning medical devices.

Other Union Legislation applicable: Not applicable

Trade name / Product name:	Mesalt
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Product Classification: MDR Class III  
 MDR Classification Rule: 4, 14  
 Sterility: Sterile  
 Measuring Function: No

This declaration is supported by a conformity assessment procedure in accordance with Annex/es: IX
Common Specification: No CS is applicable

Certificate number:	MDR 722028, MDR 722077	
Issued by:	BSi	Id No: 2797
	<i>(Notified Body Name)</i>	
<i>NB. For non-sterile, non-measuring Class I products, no certificate is issued by a Notified Body.</i>		

Mölnlycke Health Care AB issues this declaration in recognition of applied harmonized standards.

Signed for and on behalf of Mölnlycke Health Care AB

Place of Issue: Göteborg, Sweden

Date: 2022-12-20      Function: Global Regulatory Affairs Director

Name: Christina Lewing      Signature:



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<b>Generic product information</b>	
<b>Intended Purpose:</b>	Management of moderate to heavily exuding non-infected/infected wounds such as pressure ulcers, foot ulcers and deep wound management e.g. cavity wounds and fistulas.
<b>Basic UDI-DI:</b>	733243000000000013JH
<b>GMDN Code:</b>	58475 Sodium chloride dressing

<b>Product References Covered by this Declaration:</b>	<b>Product Descriptor:</b>
285280	Cleansing Dressing with 20% Sodium Chloride
285580	Cleansing Dressing with 20% Sodium Chloride
285780	Cleansing Dressing with 20% Sodium Chloride
286080	Cleansing Dressing with 20% Sodium Chloride