

# EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

## MDR 722077 R000

**Manufacturer:** Mölnlycke Health Care AB

**Address:**

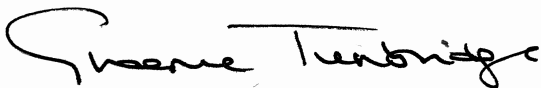
Gamlestadsvägen 3C  
Box 13080  
SE-402 52 Göteborg  
Sweden

**Single Registration Number:** Not Available

**Scope:** See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2022-03-30**

Date: **2022-03-30**

Expiry Date: **2027-03-29**

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### Device Schedule:

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Intended purpose (as per the IFU)	Risk Classification	Basic UDI-DI
Mesalt	285280	MDN 1204	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	Class III	733243000000000013JH
	285580				
	285780				
	286080				



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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.  
This certificate was issued electronically and is bound by the conditions of the contract.

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### Certificate History

*(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)*

Date	Reference Number	Action
Current	3110865	Issued



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