



Declaration of Conformity AU

Document ID: PD-798643 **Rev:** 1
Created by: Rachel Patrick
State: Released
Approved by: Masoud Alghawazi
Approval date: 2025-07-07 11:34:44
Release date: 2025-07-07 11:34:46

Title: Mepilex Border Flex Lite

Dates and times in Greenwich Mean Time, 24 hours format

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

FULL QUALITY ASSURANCE PROCEDURE

This is a declaration of conformity made under clause 1.8 of Schedule 3 to the **Therapeutic Goods (Medical Devices) Regulations 2002**

Manufacturer's name:	Mölnlycke Healthcare AB
Business address:	Entreprenörsstråket 21 SE-431 53, Mölndal SWEDEN
Medical device(s):	See attached schedule for products covered by this Declaration of Conformity.
Classification:	AU Class IIb
GMDN code and term:	See attached schedule for the GMDN code and term.
Scope of application:	See attached schedule for products to which the full quality assurance procedures applies.

Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

Full quality assurance procedures certificate:	
Certificate number:	MDR 722028
Certificate description:	European conformity assessment certificate under Annex IX chapter I and III of the Medical Devices Regulation (EU) 2017/745
Assessment body:	BSI (2797)

Design examination certificate (if applicable):	
Certificate number:	Not Applicable
Certificate description:	
Assessment body:	Not Applicable

Standards applied:	
See Essential Requirements/Principles Checklist/General Safety and Performance Requirements for standards applied.	

Authorised signatory:

Date: 2025-07-07 **Function:** QARA Commercial Director, MEA and APAC Regions

Name: Masoud Alghawazi

Signature:



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Schedule: Product list

Product Reference:	Product Descriptor:	GMDN code/term
581011	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
581100	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
581200	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
581300	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
581500	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile