



Title: AU DoC Mepiform Sterile

Document ID: PD-708175 Rev:1

Created by: Pam Hague State: Released

Approved by: Christina Lewing

Release date: 2022-03-01 15:15:43

Dates and times in Greenwich Mean Time, 24 hours format

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

This is a declaration of conformity made under clause 6.6 of Schedule 3 to the *Therapeutic Goods* (Medical Devices) Regulations 2002

Manufacturer's name:	Mölnlycke Healthcare AB	
Business address:	Gamlestadsvägen 3C	
	Box 13080	
	SE-40252, Göteborg	
	SWEDEN	
Medical device(s):	See attached schedule for products covered by this Declaration of Conformity.	
Classification:	AU Class IS	
GMDN code and term:	See attached schedule for the GMDN code and term.	
Scope of application:	See attached schedule for products to which the declaration of conformity procedures applies.	

For sterile/non-sterile Class IIa, Class I sterile devices and non-sterile Class I devices with a measuring function (if applicable):

Each kind of medical device to which the declaration of conformity procedures applies, the production quality assurance procedures have also been applied. Each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles, the classification rules, and these procedures.

For all Class I (if applicable):

Each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles and the classification rules before being supplied.

Production quality management system certificate:		
Certificate number:	MDR 722028	
-	European conformity assessment certificate under Annex IX chapter I and III of the Medical Devices Regulation (EU) 2017/745	
	BSI (2797)	

Standards applied:

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

Authorised signatory:

Date: 2022-03-01 Function: Global Regulatory Affairs Director

Name: Christina Lewing Signature:

Clumsery

Declaration of Conformity AU



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GMDN code/term

management dressing, single-use, sterile

management dressing,

management dressing, single-use, sterile

single-use, sterile

47772 Scar

47772 Scar

Title: AU DoC Mepiform Sterile

Schedule: Product list

Product Reference:

293100	Self-adherent soft silicone dressing for scar care	47772 Scar management dressing, single-use, sterile
293150	Self-adherent soft silicone dressing for scar care	47772 Scar management dressing, single-use, sterile
293199	Self-adherent soft silicone dressing for scar care	47772 Scar management dressing, single-use, sterile
293200	Self-adherent soft silicone dressing for scar care	47772 Scar management dressing, single-use, sterile
293250	Self-adherent soft silicone dressing for scar care	47772 Scar management dressing, single-use, sterile
293299	Self-adherent soft silicone dressing for scar care	47772 Scar management dressing, single-use, sterile

care

care

Self-adherent soft silicone dressing for scar 47772 Scar

Self-adherent soft silicone dressing for scar

Self-adherent soft silicone dressing for scar

Product Descriptor: