



EU Declaration of Conformity according to MDR

Title: Mölnlycke Z-Flo Fluidized Positioner, Beaded

We, Mölnlycke Health Care AB, Entreprenörstråket 21, SE-431 53, Mölndal, 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:	Mölnlycke Z-Flo Fluidized Positioner
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Product Classification: MDR Class I ns

MDR Classification Rule: 1

Sterility: Non-sterile

Measuring Function: No

This declaration is supported by a conformity assessment procedure in accordance with Annex/es: IV

Common Specification: No CS is applicable

Certificate number: Not Applicable

Issued by: Not Applicable

Id No:

(Notified Body Name)

NB. For non-sterile, non-measuring Class I products, no certificate is issued by a Notified Body.

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: Mölndal, Sweden

Date: 2025-05-06

Function:

Regulatory Affairs Excellence
Director

Name: Karin Darle Olsson

Signature:



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Generic product information	
Intended Purpose:	Mölnlycke Z-Flo Fluidized Positioner is designed to provide patient positioning, pressure redistribution and/or to offload anatomical sites, which may be used as part of a prophylactic therapy to help prevent pressure ulcers.
Basic UDI-DI:	733243000000000000J8
GMDN Code:	62292 Freestanding patient positioning mould, single-use
EMDN Code:	V080302 PATIENT POSITIONING MEDICAL CUSHIONS

Product References Covered by this Declaration:	Product	Product Descriptor:
1400902	Fluidized positioner pack	Fluidized positioning pack
1401001	Ad Small Positioner with Tab 11x22	Small positioner with tab
1401003	Ad Medium Positioner with Tab 16x30	Medium positioner with tab
1401005	Ad Large Positioner 25x36	Large positioner
1401007	Ad Small Positioner 12x20	Small positioner
1401008	Ad Small Positioner with Cover 12x20	Small positioner with cover
1401011	Ad Medium Positioner Standard 16x30	Medium positioner standard
1401105	Ad Large Positioner 25x36, China	Large positioner
1401108	Ad Small Positioner 12x20, China	Small positioner
1401111	Ad Medium Positioner Standard 16x30, China	Medium positioner standard