



**Manufacturer's
Declaration of Conformity**

Document Id: PD-701721 Rev:1
State: Released
Created by: Emilie Andersson
Title: Mölnlycke Z-Flo Fluidized
Positioner, Beaded

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We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden 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)

Note. For non-sterile, non-measuring class I products there is no Notified Body certificate

Mölnlycke Health Care issues this declaration in recognition of all applicable harmonised standards.

Signed for and on behalf of Mölnlycke Health Care

Place of Issue: Göteborg, Sweden

Date: 2021-05-26

Function: Global Regulatory Affairs Director

Name: Christina Lewing

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

Product References Covered by this Declaration:	Product Descriptor:
1400600	Small positioner with 2 tabs
1400601	Standard positioner with 2 tabs
1400902	Fluidized positioning pack
1401001	Small positioner with tab
1401003	Medium positioner with tab
1401005	Large positioner
1401007	Small positioner
1401008	Small positioner with cover
1401011	Medium positioner standard