



**EU Declaration of Conformity
according to MDR**

Document ID: PD-705080 Rev:3
Created by: Gayle Wood
State: Released
Approved by: Karin Darle Olsson
Release date: 2022-06-09 13:17:01

Title: Sterile pouches

Dates and times in Greenwich Mean Time, 24 hours format

We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, 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:	Sterile pouches
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Product Classification: MDR Class IS
MDR Classification Rule: 1
Sterility: Sterile
Measuring Function: No

This declaration is supported by a conformity assessment procedure in accordance with Annex/es: IX
Common Specification: No CS is applicable

Certificate number:	MDR 722028	
Issued by:	BSi	Id No: 2797
	(Notified Body Name)	
<i>NB. For non-sterile, non-measuring Class I products, no certificate is issued by a Notified Body.</i>		

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: Göteborg, Sweden

Date: 2022-06-09 Function: Regulatory Affairs Excellence Manager

Name: Karin Darle Olsson

Signature:



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Generic product information	
Intended Purpose:	The pouches are attached to other draped areas and are used for fluid management during surgical procedures.
Basic UDI-DI:	733243000000000034JR
GMDN Code:	56731 Surgical tissue/fluid collection bag, sterile

Product References Covered by this Declaration:	Product Descriptor:
5217	FLUID COLLECTION POUCH
5218	IRRIGATION POUCH
706035	FLUID COLLECTION POUCH
831200	IRRIGATION POUCH