



# EU Declaration of Conformity according to MDR

Document ID: PD-582073 Rev: 00  
Created by: Gayle Wood  
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Approval date: 2020-08-26

**Title:** Bulk non-sterile, pouches

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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 Medical Device Regulation 2017/745, concerning medical devices.

Other Union Legislation applicable: **Not applicable**

Trade name/ Product name:	<b>Bulk non-sterile, pouches</b>
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Product classification: **I**  
MDR Classification Rule: **1**  
Sterility: **Non-sterile**  
Measuring function: **No**

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

Certificate number:	<b>Not Applicable</b>
Issued by:	<b>Not Applicable</b>
NB. For non sterile, non-measuring Class I products, no certificate is issued by a Notified Body.	

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

Signed for and on behalf of Mölnlycke Health Care

Date: **2020-08-26** Function: **Regulatory Affairs Director**

Name: **Christina Lewing**

Signature:

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Intended Purpose: The pouches are attached to other draped areas and are used for fluid management during surgical procedures. The pouches are provided non-sterile for final packaging and sterilisation prior to use.

**Product(s) covered by this declaration:**

Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
815310	IRRIGATION POUCH	733243000000000009JS	58982 Surgical tissue/fluid collection bag, non-sterile
9317	FLUID COLLECTION POUCH	733243000000000009JS	58982 Surgical tissue/fluid collection bag, non-sterile
9318	OPHTHALMIC DRAINAGE POUCH	733243000000000009JS	58982 Surgical tissue/fluid collection bag, non-sterile
976035	FLUID COLLECTION POUCH	733243000000000009JS	58982 Surgical tissue/fluid collection bag, non-sterile
983200	FLUID COLLECTION POUCH W/INCISE	733243000000000009JS	58982 Surgical tissue/fluid collection bag, non-sterile
9901	IRRIGATION POUCH	733243000000000009JS	58982 Surgical tissue/fluid collection bag, non-sterile