Mölnlycke[®]

Declaration of Conformity EU

Document ID: Created by: Approved by: Approval date: PD-605028 Rev: 00 Gayle Wood Karin Darle Olsson 2021-02-02

Title: Sterile pouches Page 1(2)

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 Council Directive 93/42/EEC of 14 June 1993, as amended by 2007/47/EEC, concerning medical devices, the Medical Devices Act SFS 1993:584 and the Swedish Medical Product Agency regulations and guidelines: Medical Devices, LVFS 2003:11, as amended by LVFS 2009:18.

Trade name/
Product name:

Sterile pouches

Product classification: IS

Sterility Status: Sterile

Measuring function: No

This declaration is supported by a conformity assessment procedure in accordance with

Annex/es: V

Certificate number: CE 01966

Issued by: **BSI (2797)**

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 AB Care

Date: 2021-02-02 Function: Regulatory Affairs Manager

Compliance

Name: Karin Darle Olsson Signature:

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Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
5217	FLUID COLLECTION POUCH	56731 Surgical tissue/fluid collection bag, sterile
5218	IRRIGATION POUCH	56731 Surgical tissue/fluid collection bag, sterile
831200	IRRIGATION POUCH	56731 Surgical tissue/fluid collection bag, sterile

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