# EU Declaration of Conformity according to MDR

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| **Document ID:** | PD-705011 **Rev:**2 |
| **Created by:** | Gayle Wood |
| **State:** | Released |
| **Approved by:** | Karin Darle Olsson |
| **Release date:** | 2022-06-09 13:17:02 |

Dates and times in Greenwich Mean Time, 24 hours format

**Title:** Sterile dislocation bag

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

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| Trade name / Product name: | Sterile bag |

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| Product Classification: | MDR Class IS |
| MDR Classification Rule: | 1 |
| Sterility: | Sterile |
| Measuring Function: | No |

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

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| Certificate number: | MDR 722028 | | |
| Issued by: | BSi | Id No: | 2797 |
| | *(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: Göteborg, Sweden

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

Name: Karin Darle Olsson Signature: 

| **Generic product information** | |
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| **Intended Purpose:** | The Dislocation Bag is attached to other draped areas and used to maintain a dislocated leg within the sterile field during a surgical procedure. |
| **Basic UDI-DI:** | 733243000000000179KL |
| **GMDN Code:** | 47783 Patient surgical drape, single-use |

| **Product References Covered by this Declaration:** | **Product Descriptor:** |
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| 84541230 | DISLOCATION BAG |