By Royal Charter

# EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

## MDR 758927 R000

**Manufacturer:** Mölnlycke Health Care AB

**Address:**
Gamlestadsvägen 3C
Box 13080
SE-402 52 Göteborg
Sweden

**Single Registration Number:** Not Available

**Scope:** See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2022-02-18** Date: **2022-02-18** Expiry Date: **2027-02-17**

...making excellence a habit.™

# EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

## MDR 758927 R000

### Device Schedule:

| Device Name | Model | Type (Codes as per (EU) 2017/2185) | Intended purpose (as per the IFU) | Risk Classification | Basic UDI-DI |
|---|---|---|---|---|---|
| Mepilex Border Ag | 382000<br>382200<br>382400<br>395010<br>395200<br>395221<br>395260<br>395300<br>395360<br>395400<br>395410<br>395460<br>395600<br>395660<br>395700<br>395800<br>395900 | MDN 1204 | Management of medium to high exuding wounds leg and foot ulcers, pressure ulcers, malignant wounds, partial thickness burns, traumatic and surgical wounds where a moist environment, exudate handling, gentle fixation and an antimicrobial action is indicated<br><br>May be used on infected wounds as part of a treatment regimen under supervision of a qualified health care professional<br><br>Can be used under compression bandaging | Class III | 733243000000000028JW |

First Issued: **2022-02-18** Date: **2022-02-18** Expiry Date: **2027-02-17**

...making excellence a habit.™

# EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

## MDR 758927 R000

### Certificate History

*(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)*

| Date | Reference Number | Action |
|---|---|---|
| Current | 3371632 | Issued |

First Issued: **2022-02-18** Date: **2022-02-18** Expiry Date: **2027-02-17**

...making excellence a habit.™