

Declaration of Conformity

Product details:

| Product name: | | GTIN | Product Revision | Item number manufacturer: | Item number Distributor Mölnlycke | Classification acc. 93/42/EEC. |
|--|--------|---------------|---------------------|------------------------------|---|--------------------------------------|
| Granudacyn® Wound Irrigation Solution | 50ml | 9120073780997 | 1 | 350500 | 360150 | IIb |
| Granudacyn® Wound Irrigation Solution | 250ml | 9120073781000 | 2 | 350400 | 360100 | IIb |
| Granudacyn® Wound Irrigation Solution | 500ml | 9120073781017 | 1 | 350050 | 360101 | IIb |
| Granudacyn® Wound Irrigation Solution | 1000ml | 9120073781024 | 1 | 350100 | 360102 | IIb |
| Granudacyn® Wound Irrigation Solution NPWT | 500ml | 9120073781031 | 1 | 350200 | 360103 | IIb |
| Granudacyn® Wound Irrigation Solution NPWT | 1000ml | 9120073781048 | 2 | 350300 | 360104 | IIb |
| Granudacyn® Wound Gel | 50g | 9120073781055 | 2 | 351050 | 360107 | IIb |
| Granudacyn® Wound Gel | 100g | 9120073781062 | 2 | 351150 | 360108 | IIb |
| Granudacyn® Wound Gel | 250g | 9120073781079 | 2 | 351250 | 360106 | IIb |

GMDN-Code: 59523 - Antimicrobial wound irrigation solution, non-sterile

UMDNS-Code: 14-462 - Irrigation Kits, Wound

Assessment details:

| | | |
|-------------------------------|---|---------------------|
| Notified body: | TÜV Nord CERT GmbH, Langemarckstraße 20, D 45141 Essen | |
| Route of directive 93/42/EEC: | Annex II (Full quality assurance system) except section 4 | |
| Certificates: | EC-Certificate: Reg.-No. 44 232 160605, Report No. 3524 7195 | |
| | ISO Certificate: Reg.-No. 44 221 160605, Report No. 3524 7194 | |
| Applied harmonized standards: | EN ISO 13485:2016 | EN ISO 14971:2012 |
| | EN 1041:2008 | EN 62366:2008 |
| | EN ISO 10993-1:2009 | EN ISO 15223-1:2016 |
| | EN ISO 10993-5:2009 | |

We declare under sole responsibility that the products described above as delivered are in compliance with directive 93/42/EEC including change directive 2007/47/EC and the Austrian medical-device-law BGBl. 657/1996.

The products are CE marked.

This Declaration of Conformity expires with the expiration of the EC-Certificate, latest on May 26th 2024.

CE 0044

Elixhausen, 27.02.2020

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