P.G.F. Industry
SOLUTIONS GmbH

Manufacturer:
P.G.F. INDUSTRY SOLUTIONS GmbH
Katzmoosstraße 26a, A - 5161 Elixhausen
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UID: ATU61934955/FN 265002i
SRN: AT-MF-000000310

# Declaration of Conformity

**Product details:**

| Product name: | | GTIN | Product Revision | Item number Manufacturer: | Item number Dealer Mölnlycke | Classification according to 93/42/EEC |
|---|---|---|---|---|---|---|
| Granudacyn® Wound Irrigation Solution | 50ml | 9120073780997 | 1 | 350500 | 360150 | IIb (4) |
| Granudacyn® Wound Irrigation Solution | 50ml | 9120073781246 | 1 | 350550 | 360110 | IIb (4) |
| Granudacyn® Wound Irrigation Solution | 250ml | 9120073781000 | 2 | 350400 | 360100 | IIb (4) |
| Granudacyn® Wound Irrigation Solution | 250ml | 9120073781253 | 1 | 350450 | 360111 | IIb (4) |
| Granudacyn® Wound Irrigation Solution | 500ml | 9120073781017 | 2 | 350050 | 360101 | IIb (4) |
| Granudacyn® Wound Irrigation Solution | 1000ml | 9120073781024 | 1 | 350100 | 360102 | IIb (4) |
| Granudacyn® Wound Irrigation Solution NPWT | 500ml | 9120073781031 | 1 | 350200 | 360103 | IIb (4) |
| Granudacyn® Wound Irrigation Solution NPWT | 1000ml | 9120073781048 | 2 | 350300 | 360104 | IIb (4) |
| Granudacyn® Wound Gel | 50g | 9120073781055 | 2 | 351050 | 360107 | IIb (4) |
| Granudacyn® Wound Gel | 100g | 9120073781062 | 2 | 351150 | 360108 | IIb (4) |
| Granudacyn® Wound Gel | 100g | 9120073781260 | 1 | 351100 | 360112 | IIb (4) |
| Granudacyn® Wound Gel | 200g | 9120073781277 | 1 | 351200 | 360113 | IIb (4) |
| Granudacyn® Wound Gel | 250g | 9120073781079 | 2 | 351250 | 360106 | IIb (4) |

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|---|---|
| Basic UDI-DI Wound Irrigation Solution: | 912007378WISJX |
| GMDN code Wound Irrigation Solution: | 58931 - Non-antimicrobial wound irrigation soultion, non-sterile |
| Basic UDI-DI Wound Gel: | 912007378WGRV |
| GMDN code Wound Gel | 64596 - Gel for wound healing, non-sterile |
| UMDNS code: | 14-462 - Irrigation kit, wound |

**Assessment details:**

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|---|---|---|
| Notified body: | TÜV NORD CERT GmbH, Am TÜV 1, 45307 Essen, Germany | |
| Procedure according to Directive 93/42/EEC: | Annex II (full quality assurance system) without section 4 | |
| Certificates: | EC certificate: Reg. no. 44 232 160605, report no. 3524 7195 | |
| | ISO CertifiCate: Reg. no. 44 221 160605, Report no. 3536 7188 | |
| Essential standards: | DIN EN ISO 13485 | DIN EN ISO 14971 |
| | DIN EN ISO 10993-1 | DIN EN ISO 10993-3 |
| | DIN EN ISO 10993-5 | DIN EN ISO 10993-10 |
| | DIN EN ISO 10993-11 | DIN EN ISO 10993-18 |
| | DIN EN 62366 | ISO 20417 |
| | EN ISO 15223-1 | ISO 11737-1 |

We declare under our sole responsibility that the products listed above, as supplied, comply with the essential requirements of Directive 93/42/EEC on medical devices, including the amendments to Directive 2007/47/EC. The products are labelled with a CE mark. For existing products for which a valid EC certificate was issued in accordance with Directive 93/42/EEC, the transitional provision in accordance with Art. 120 (2) of Regulation (EU) 2017/745 of 2017-04-05 and Regulation (EU) 2023/607 of 2023-03-15 applies. The extended validity date for the EC certificate with the no. 44 232 160605 is therefore 2028-12-31.

CE 0044

Elixhausen, 22.05.2024

Dr. Elisabeth Landertinger
(Director QM/RA)