

We,

**BSN medical GmbH  
Schützenstr. 1-3  
22761 Hamburg  
Germany  
(SRN: DE-MF-000005787)**

hereby declare under our sole responsibility, that this product family complies with the applicable requirements of the regulation (EU) 2017/745 of the European parliament and of the council on medical devices (MDR).

Product Name:

**Leukopor®**

Basic UDI-DI:

**40428094003457397**

Intended purpose:

**Leukopor® is intended for short time use on intact skin for fixation of dressings of all types and sizes, securing electrodes or other measuring devices, fixation and securing of probes, tubes and catheters.**

Conformity assessment route: **Annex II+III**

Classification rule: **1**

Classification: **I**

The Declaration of Conformity is performed in accordance with the quality management system according to EN ISO 13485, and fulfils the general safety and performance requirements of the regulation (EU) 2017/745.

Date of Issue: 05.05.2023

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Compiled and released:

Hamburg, 05.05.2023  
Martin Spengler  
Director Regulatory Affairs Hamburg  
BSN medical GmbH



| Article        | Description  | REF      |
|----------------|--|----------|
| 02453-00000-10 | LEUKOPOR PLASTIC CORE 1.25CMX9.2M<br>WHITE 1 FI FR EN DA DE SV PT NL N IT EL<br>(24/BOX)   | 02453-00 |
| 02454-00000-10 | LEUKOPOR PLASTIC CORE 2.5CMX9.2M<br>WHITE 1 DA NL EN FI FR DE EL IT NO PT SV<br>12/BOX     | 02454-00 |
| 02455-00000-10 | LEUKOPOR PLASTIC CORE 5CMX9.2M WHITE<br>1 FI FR EN DA DE SV PT NL EL IT N (6/BOX)          | 02455-00 |
| 02456-00000-10 | LEUKOPOR PLASTIC CORE 7.5CMX9.2M<br>WHITE 1 DE DA EN FI FR EL IT NL NO PT SV<br>4/BOX      | 02456-00 |
| 02471-00000-12 | LEUKOPOR PLASTIC SNAP RING 1.25CMX5M<br>WHITE 1 DA NL EN FI FR DE EL IT NO ES SV<br>24/BOX | 02471-00 |
| 02471-00004-04 | LEUKOPOR PLASTIC SNAP RING<br>BLISTERCARD 1.25CMX5M WHITE 1 NL FR DE                       | 02471-04 |
| 02471-00005-12 | LEUKOPOR PLASTIC SNAP RING 1.25CMX5M<br>WHITE 1 IT MUTUA 02471-00-12                       | 02471-05 |
| 02472-00000-12 | LEUKOPOR PLASTIC SNAP RING 2.5CMX5M<br>WHITE 1 DA NL EN FI FR DE EL IT NO ES SV<br>12/BOX  | 02472-00 |
| 02472-00003-04 | LEUKOPOR PLASTIC SNAP RING<br>BLISTERCARD 2.5CMX5M WHITE 1 NL FR DE                        | 02472-03 |
| 02472-00004-12 | LEUKOPOR PLASTIC SNAP RING 2.5CMX5M<br>WHITE 1 IT MUTUA 02472-00-12                        | 02472-04 |
| 02474-00000-12 | LEUKOPOR PLASTIC SNAP RING 5CMX5M<br>WHITE 1 DA NL EN FI FR DE EL IT NO ES SV<br>6/BOX     | 02474-00 |
| 02474-00001-12 | LEUKOPOR PLASTIC SNAP RING 5CMX5M<br>WHITE 1 IT MUTUA 02474-00-12                          | 02474-01 |
| 02481-00000-12 | LEUKOPOR PLASTIC SPOOL 1.25CMX5M<br>WHITE 1 DA NL EN FI FR DE EL IT NO ES SV<br>24/BOX     | 02481-00 |
| 02482-00000-12 | LEUKOPOR PLASTIC SPOOL 2.5CMX5M WHITE<br>1 DA NL EN FI FR DE EL IT NO ES SV 12/BOX         | 02482-00 |
| 02484-00000-12 | LEUKOPOR PLASTIC SPOOL 5CMX5M WHITE 1<br>DA NL EN FI FR DE EL IT NO ES SV 6/BOX            | 02484-00 |
| 47451-00000-07 | LEUKOPOR PLASTIC SPOOL 1.25CMX5M   | 47451-00 |

| Article        | Description  | REF      |
|----------------|--|----------|
|                | WHITE 1 ES 1/BOX                                       |          |
| 47452-00000-07 | LEUKOPOR PLASTIC SPOOL 2.5CMX5M WHITE<br>1 ES 1/BOX    | 47452-00 |
| 47454-00000-07 | LEUKOPOR PLASTIC SPOOL 5CMX5M WHITE 1<br>ES 1/BOX      | 47454-00 |
| 47456-00000-07 | LEUKOPOR PLASTIC SPOOL 10CMX10M<br>WHITE 1 ES 1/BOX    | 47456-00 |
| 76446-00000-05 | LEUKOPOR DISPENSER 1.25CMX9.2M WHITE<br>1 NL FR DE     | 76446-00 |
| 76446-00001-02 | LEUKOPOR DISPENSER 1.25CMX9.2M WHITE<br>1 IT           | 76446-01 |
| 76447-00000-05 | LEUKOPOR DISPENSER 2.5CMX9.2M WHITE 1<br>DE FR NL      | 76447-00 |
| 76447-00001-02 | LEUKOPOR DISPENSER 2.5CMX9.2M WHITE 1<br>IT ES         | 76447-01 |
| 76447-00002-05 | LEUKOPOR DISPENSER 2.5CMX9.2M 1 FR<br>LPPR 76447-00-05 | 76447-02 |