

**Legal Manufacturer**

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| Abena AB Ljungadalsgatan 19 35246 Växjö Sweden | www.finesshygiene.com Phone: +46 494 151 00 Mail: info@finesshygiene.com |
| - Single Registration Number (SRN) | SE-MF-000030220 |

Medical Device(s)

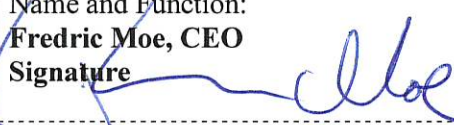
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|--|---|
| - Basic UDI-DI | 7331246PRSH4V |
| - Product/trade name(s) and/or product code(s) (REF)/and or catalogue number | Disposable protective sheets |
| - Other ref. allowing identification (e.g. UDI-DI) | Appendix I |
| - Intended Purpose | The protective sheets are reducing the risk for contamination for healthcare professionals and next user by absorbing leakage body liquids. |
| - Risk classification | Class I according to rule no.I in MDR annex VIII |
| - Conformity route | MDR Annex II and III |

Other information (if applicable)

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| - Common Specifications used for compliance | Annex II |
| - Notified Body name and identification no. and description of the conformity assessment procedure performed | N/A |
| - Additional information | N/A |
| - Standards used to assure compliance | Appendix II |

The above mention manufacturer hereby declare that the above mentioned medical device(s) are compliant with the EU Regulation 2017/745 for Medical Devices and the EU legislations mentioned under "additional information".

This Declaration of Conformity is issued under the sole responsibility of the above mentioned manufacturer.

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| Name and Function: Fredric Moe, CEO Signature  | Place and date of issue Växjö, SE, 04.07.2025 |
| Abena AB, Ljungadalsgatan 19, 352 46 Växjö, Sweden | |

Appendix I, List of products

| Art.no: | Product name: | Sizes: |
|----------------|----------------------------------|---------------|
| 65005 | Bio | 80x210 cm |
| 65006 | Bio | 80x175 cm |
| 65007 | Bio | 80x140 cm |
| 65008 | Bio | 37x44 cm |
| 72011 | Regular, Bulk | 80x140 cm |
| 72031 | Regular | 80x180 cm |
| 72073 | Regular, Bulk | 80x210 cm |
| 72080 | Regular | 150x210 cm |
| 72081 | Regular | 80x250 cm |
| 72578 | Regular, Inner bag | 80x210 cm |
| 72611 | Regular, Inner bag | 80x140 cm |
| 73445 | Regular | 80x60 cm |
| 73448 | Regular | 80x90 cm |
| 73446 | Regular, Reinhardt | 80x90 cm |
| 72516 | Basic Regular | 80x140 cm |
| 72517 | Basic Regular | 80x210 cm |
| 72201 | Light | 80x140 cm |
| 72206 | Light | 80x100 cm |
| 72222 | Light, Inner bag | 80x175 cm |
| 72224 | Light | 150x210 cm |
| 72240 | Light, Bulk | 80x175 cm |
| 72243 | Light, Reinhardt | 80x175 cm |
| 72246 | Light, To be loaded in container | 80x175 cm |
| 72260 | Light, Bulk | 80x210 cm |
| 72263 | Light, Reinhardt | 80x210 cm |
| 72281 | Light | 95x200 cm |
| 72601 | Light, Full height pallet | 80x175 cm |
| 72602 | Light, Full height pallet | 80x210 cm |
| 72608 | Light, Inner bag | 80x210 cm |
| 73444 | Light | 80x60 cm |
| 72232 | Ultra Light | 80x175 cm |
| 72432 | Super Soft | 80x170 cm |
| 72433 | Super Soft | 79x170 cm |
| 72441 | Super Soft | 80x220 cm |
| 1000031138 | Super Soft | 80x210 cm |
| 73432 | Super Soft | 39x59 cm |
| 73434 | Super Soft | 38x50 cm |
| 72700 | Super Soft | 39x29 cm |
| 73461 | Premier/Comfort | 50x40 cm |
| 81509 | TE27N, Reinhardt | 37,5x39 cm |
| 81510 | TE27N, Bulk | 37,5x29 cm |
| 81511 | TE27N, Bulk | 37,5x39 cm |
| 81512 | TE27N | 37,5x50 cm |
| 81516 (6240) | TE27N, Inner bag | 37,5x29 cm |
| 81517 (6238) | TE27N, Inner bag | 37,5x39 cm |
| 500121 | Small protective sheet | 37x50 cm |
| 90049 | Small protective sheet | 37x40 cm |
| 72518 | Basic Regular | 80x175 cm |

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|------------|---------------------------------------|------------|
| 72575 | Regular | 80x175 cm |
| 72612 | Super Soft | 80x170 cm |
| 90050 | Small protective sheet, Cardboard bag | 37x40 cm |
| 72613 | Super soft | 80x240 cm |
| 1000024398 | Small protective sheet | 60x60 cm |
| 1000024400 | Small protective sheet | 80x80 cm |
| 1000024502 | TE27N, Cardboard bag | 37,5x50 cm |
| 1000024503 | Regular, Cardboard bag | 80x90 cm |
| 1000025244 | Small protective sheet | 60x58 cm |
| 1000025233 | Regular, white | 80x210 cm |
| 1000030815 | Small protective sheet, unfolded | 80x80 cm |
| 1000030816 | Small protective sheet, unfolded | 80x90 cm |
| 1000027370 | Small protective sheet, unfolded | 21x35 cm |

Appendix II, List of applicable standards used

| No. | Document no. | Document title |
|-----|---------------------|--|
| 1 | MDR 2017/745 | Medical Device Regulation (EU) |
| 2 | EN ISO 13485:2016 | Medical Devices – Quality Management System |
| 3 | EN ISO 14971:2019 | Medical Devices - Application of risk management to medical devices |
| 4 | EN ISO 15223-1:2021 | Medical Devices – Symbols to be used with medical devices labels, labelling and information to be supplied |
| 5 | EN ISO 9001:2015 | Quality Management System - requirements |
| 6 | EN ISO 14001:2015 | Environmental Management Systems – Requirements with guidance for use |
| 7 | EN ISO 10993-1:2020 | Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process |
| 8 | EN ISO 11948-1:1996 | Rothwell Method |

Appendix III, Disposable protective sheet variants:

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| Light | 2 x white tissue + blue threads + transparent PE + blue fluid barriers |
| Ultra Light | White tissue + blue threads + transparent PE + blue fluid barriers |
| Reinforced | 2 x white tissue + blue threads + transparent PE + blue fluid barriers |
| Premier/Comfort | White tissue + blue PE + fluid barriers |
| Super Soft | White airlaid + transparent PE + fluid barriers |
| Regular | White tissue + blue PE + fluid barriers |
| Regular, white | White tissue + transparent PE + fluid barriers |
| Standard | White tissue + blue PE + fluid barriers |
| Basic Regular | Recycled tissue + blue PE + fluid barriers |
| Basic Ultra Light | Recycled tissue + blue threads + transparent PE + blue fluid barriers |
| Economy | White tissue + blue PE |
| Bio | White tissue + film + fluid barriers |
| TE27N | White tissue + blue PE |
| Small protective sheet | White tissue + transparent PE |
| Small protective sheet | White tissue + blue PE |