



EU Declaration of Conformity – PPE

Manufacturer

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

The above mentioned manufacturer hereby declare that the above mentioned products are compliant with

- EU Regulation 2016/425 for personal protective equipment
- Regulation 2016/425 and the Personal Protective Equipment (Enforcement) Regulations 2018: Great Britain

Other information (if applicable)

- PPE category and risk	EU 2016/425 CAT I For minimal risk only
- Standards and classifications used to assure compliance incl. date of the standards	ISO 9001 ISO 13485
- Notified body name and identification number	N/A – CAT I products
- EU type-examination certificate number	N/A – CAT I products
- Assessment procedure:	Module A

Consent

Signed on behalf of: Name and function: Louise Risager, Global Product Manager	Place and date:
Signature <i>Louise Risager</i> ----- Abena, Egelund 35, DK-6200 Aabenraa	Aabenraa, DK, 02.10.2025



Product

Products type, batch or item number	Product name (product)
210691	Visitor jacket, ABENA Classic, S/M, white, PP, non-sterile, single use
210692	Visitor jacket, ABENA Classic, L-XL, white, PP, non-sterile, single use
210693	Visitor jacket, ABENA Classic, XXL/3XL, white, PP, non-sterile, single use
1000002831	Visitor jacket, ABENA Classic, L, blue, PP, non-sterile, single use
1000002832	Visitor jacket, ABENA Classic, L/XL, white, PP, non-sterile, single use
1000026344	Visitor jacket, ABENA Classic, 2XL/3XL, white, PP, non-sterile, single use
1000028011	Visitor jacket, ABENA Classic, L-XL, white, PP, non-sterile, single use
1999905474	Visitor jacket, ABENA Classic, S/M, dark blue, PP, non-sterile, single use
1999905476	Visitor jacket, ABENA Classic, L-XL, dark blue, PP, non-sterile, single use
1999905478	Visitor jacket, ABENA Classic, XXL/3XL, dark blue, PP, non-sterile, single use
1999918623	Visitor jacket, ABENA Classic, S/M, white, PP, non-sterile, single use
1999918624	Visitor jacket, ABENA Classic, L-XL, white, PP, non-sterile, single use
1000031593	Visitor jacket, ABENA Classic, L-XL, white, PP, non-sterile, single use

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