



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 13485
- Notified body name and identification number	N/A
- EU type-examination certificate number	N/A
- Assessment procedure:	Module A of PPE Regulation 2016/425 for category I

Consent

Signed on behalf of: Name and function: Tina Jønson, Global Category Manager Signature 	Place and date: Aabenraa, DK, 12-02-2024
Abena, Egelund 35, DK-6200 Aabenraa	

Product

Product number	Product name (product)
1000006719	Sleeve cover, ABENA, 40x20cm, 20 micron, white, LDPE, non-sterile
1000006721	Sleeve cover, ABENA, 40x20cm, 30 micron, blue, LDPE, non-sterile
1000012336	Sleeve cover, ABENA, 40x20cm, 20 micron, blue, LDPE, non-sterile, single use
1010001526	Sleeve cover, ABENA, 40x20cm, white, PE/PP, single use
1999903027	Sleeve cover, 40x20 cm, 20 micron, blue
1999903397	Sleeve cover, ABENA, 40x20cm, 20 micron, blue, LDPE, non-sterile

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