



## EU Declaration of Conformity

### Legal Manufacturer

- Name	ABENA A/S	www.abena.com
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- Single Registration Number (SRN), if applicable	DK-MF-000002482	

### Medical Device(s)


- Basic UDI-DI	570353800MeVF-00I-06001MS
- Product/trade name(s) and/or product code(s) (REF)/and or catalogue number	Vinyl Medical Examination Gloves, Powder-Free
- Other ref. allowing identification (e.g. UDI-DI)	-
- Intended Purpose	Vinyl Examination gloves are intended to be worn by healthcare practitioners to protect patient and user from cross-contamination.
- Risk classification	Class 1 according to rule no. 1 and 5 in MDR annex VIII

### Other information (if applicable)

- Common Specifications used for compliance	
- Notified Body name and identification no. and description of the conformity assessment procedure performed	SATRA Technology Europe Limited Bracetown Business Park Clonee D15YN2P Ireland
- Additional information	EU Type Examination Module B and On-going conformity Module C2 performed by notified body 2777, SATRA Technology Europe Limited. Issued EU Type Examination certificate number 2777/11628/E02-01
- Standards used to assure compliance	EU 2016/425, EN374-1:2016 Type C, EN374-4:2013, EN374-5:2016 Virus, EN16523-1:2015

The above mentioned 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.

Name and Function: <b>Khalid Elamri, Global Category Manager</b> Signature 	<b>Place and date of issue</b>  Aabenraa, DK, 17-05-2021
Abena, Egelund 35, DK-6200 Aabenraa	

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## Appendix I, List of products

Product Name	Item no.	UDI-DI	Intended Purpose
Classic Vinyl Examination gloves powder free transparent colour, 100 pcs	4431,4424-4426,4430	-	Protect patient and user from cross-contamination.

## Appendix II, List of applicable standards used

Product Name	Standards used
Vinyl Examination gloves powder free	EN 455-1:2002
Vinyl Examination gloves powder free	EN 455-2:2015
Vinyl Examination gloves powder free	EN 455-3:2015
Vinyl Examination gloves powder free	EN 455-4:2009
Vinyl Examination gloves powder free	EN374-1:2016
Vinyl Examination gloves powder free	EN374-2:2003
Vinyl Examination gloves powder free	EN374-4:2013
Vinyl Examination gloves powder free	EN374-5:2016
Vinyl Examination gloves powder free	EN16523-1:2015
Vinyl Examination gloves powder free	EN420:2003

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