



EU Declaration of Conformity

Legal Manufacturer

- Name	ABENA A/S	www.abena.com
- Address	Egelund 35	Phone: +45 7431 1818
- Phone / fax / email / webpage	DK-6200 Aabenraa Denmark	Fax: +45 7462 9737 Mail: info@abena.com
	Distributor:	Distributor :
	E. Weber & Cie AG, Industriestrasse 28, 8157 Dielsdorf Switzerland	www.webstar.ch Phone: +41 44 870 87 00 Fax: +41 44 870 87 20 Mail: info@webstar.ch
- Single Registration Number (SRN), if applicable	-	

Medical Device(s)

- Basic UDI-DI	-
- Product/trade name(s) and/or product code(s) (REF)/and or catalogue number	Nitril Medical Examination Gloves, Powder-Free
- Other ref. allowing identification (e.g. UDI-DI)	-
- Intended Purpose	Nitrile 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	Centexbel Technologiepark 70, BE 9052 Gent Belgium
- Additional information	EU Type Examination Module B by Notified Body 0493 and On-going conformity Module D performed by notified body 0598 SGS Fimko Oy. EU Type Examination certificate issued by NB 0493: Ref. certificate 045/2019/0381.
- Standards used to assure compliance	EU2016/425, EN374-1:2016 Type C, EN374-2:2003, EN374-4:2013, EN374-5:2016, EN16523-1:2015, EN455 1-4

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: Khalid Elamri, Global Category Manager	Place and date of issue
Signature 	Aabenraa, DK, 23-04-2020
Abena, Egelund 35, DK-6200 Aabenraa	

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Appendix I, List of products

Product Name	Item no.	UDI-DI	Intended Purpose
Nitril Examination gloves powder free Blue 100, Starline	33438-33442 (1000013926-30)	-	Protect patient and user from cross-contamination
Nitril Examination gloves powder free White 100 Starline	33443-33447 (1000013868-72)	-	Protect patient and user from cross-contamination
Nitril Examination gloves powder free White 200 Starline	33448-33452 (1000013917-21)	-	Protect patient and user from cross-contamination
Nitril Examination gloves powder free Blue 200 Starline	33487-33491 (1000013931-35)	-	Protect patient and user from cross-contamination

Appendix II, List of applicable standards used

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

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