



EU Declaration of Conformity

Legal Manufacturer

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- Single Registration Number (SRN), if applicable	DK-MF-000002482	

Medical Device(s)


- Basic UDI-DI	570353800MeLF-00I-06003AC
- Product/trade name(s) and/or product code(s) (REF)/and or catalogue number	Latex Medical Examination Gloves, Powdered
- Other ref. allowing identification (e.g. UDI-DI)	-
- Intended Purpose	Latex 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	PPE Regulation (EU) 2016/425 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 2777/10905-01/E03-01
- Standards used to assure compliance	EN374-1:2016 Type B, 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: Khalid Elamri, Global Category Manager	Place and date of issue Aabenraa, DK, 06-09-2021
Signature 	
Abena, Egelund 35, DK-6200 Aabenraa	

Template Responsible: JOHO	Created: JOHO	Approved: ULDA
File: Medical-Exam-Latex-Glove-Powdered 4382-4386_3936-3939 Type B	Revision/Version: 1.1	Date: 19-08-2020
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Appendix I, List of products

Product Name	Item no.	UDI-DI	Intended Purpose
Classic Latex Examination gloves powdered natural and blue colour, 100 pcs	4382 - 4386 3936 - 3939	-	Protect patient and user from cross-contamination.

Appendix II, List of applicable standards used

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

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