



Single 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	Please see appendix I
- Product/trade name(s) and/or product code(s) (REF)/and or catalogue number	Please see appendix I
- Other ref. allowing identification (e.g. UDI-DI)	Please see appendix I
- Intended Purpose	Please see appendix I
- Conformity assessment:	MDR art. 52.7, annex II and annex III
- Risk classification	Class 1 according to rule no. 1 and 5 in MDR annex VIII

Other information (if applicable)

- Common Specifications used for compliance	-
- Additional information	Device also compliant to Personal Protective Equipment regulation (EU) 2016/425 under the mentioned notified body assessment.
- Notified Body name and identification no. and description of the conformity assessment procedure performed	CAT III CE certified at BSI Group The Netherlands CE2797 EU type certificate assessed by CE 2777 notified body SATRA Technology Europe. Module B certificate 2777/ 10013-05/E05-01 Module D on-going certification is assessed by CE2797 BSI Group The Netherlands
- Standards used to assure compliance	Please see appendix II

The above mentioned manufacturer hereby declares that the below 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: Jakob Lei, Global Category Manager Signature 	Place and date of issue Aabenraa, DK, 09-02-2024
Abena, Egelund 35, DK-6200 Aabenraa	

Template Responsible: JOHO	Created: JOHO	Approved: ULDA
File: File: Abena Single DoC External MDR Accelerator free Nitrile low derma 2024, PPE	Revision/Version: 1.5	Date: 2022-11-02
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Appendix I, List of products

Product Name	Item no.	Basic UDI-DI	EMDN code	Intended Purpose
Excellent Nitril Examination gloves Accelerator and powder free blue colour, 100 pcs	290400-290404	57035380MeNAf-00I-060013F	T01020204	Protect patient and user from cross-contamination.
Excellent Nitril Examination gloves Accelerator and powder free blue colour, 150 pcs	290670-290674	57035380MeNAf-00I-060013F	T01020204	Protect patient and user from cross-contamination.
Excellent Nitril Examination gloves Accelerator and powder free blue colour, long cuff, 100 pcs	290405-290409	57035380MeNAf-00I-060013F	T01020204	Protect patient and user from cross-contamination.
Excellent Nitril Examination gloves Accelerator and powder free blue, 200 pcs, low derma	1000006803-1000006807, 1999917792	57035380MeNAf-00I-060013F	T01020204	Protect patient and user from cross-contamination.
Excellent Nitril Examination gloves Accelerator and powder free blue, 100 pcs, low derma	1000008823-1000008819	57035380MeNAf-00I-060013F	T01020204	Protect patient and user from cross-contamination.
Excellent Nitril Examination gloves Accelerator and powder free black, 100 pcs, low derma	1999916946-50, 1999917795	57035380MeNAf-00I-060013F	T01020204	Protect patient and user from cross-contamination.

Appendix II, List of applicable standards used

Standard title	Reference
Medical gloves for single use: Requirements and testing for freedom from holes	EN 455-1:2020
Medical gloves for single use Requirements and testing for physical properties	EN 455-2:2015
Medical gloves for single use Requirements and testing for biological evaluation	EN 455-3:2024
Medical gloves for single use - Part 4: Requirements and testing for shelf life determination	EN 455-4:2009
Protective gloves against dangerous chemicals and micro-organisms Terminology and performance requirements for chemical risks	EN ISO 374-1:2016
Protective gloves against dangerous chemicals and micro-organisms Determination of resistance to degradation by chemicals	EN ISO 374-4:2019
Protective gloves against dangerous chemicals and micro-organisms Terminology and performance requirements for micro-organisms risks	EN ISO 374-5:2016
Determination of material resistance to permeation by chemicals - Part 1: Permeation by potentially hazardous liquid chemicals under conditions of continuous contact	EN 16523-1:2015
Protective gloves. General requirements and test methods	EN ISO 21420:2020

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