



EU Declaration of Conformity

Legal Manufacturer

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|------------------------------------|-----------------------------|--|
| - 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 |
| - Single Registration Number (SRN) | DK-MF-000002482 | |

Medical Device(s)


| | |
|---|--|
| - Intended Purpose | Nitrile examination gloves are intended to protect patient and user from cross-contamination |
| - Product/trade name(s) and product code(s) (REF)/and or catalogue number | Please see appendix I |
| - Basic UDI-DI | Please see appendix I |
| - Other ref. allowing identification (e.g. UDI-DI) | Please see appendix I |
| - EMDN (no. and term) | Please see appendix I |
| - Risk classification | Class I according to rule no.1 + 5, MDR annex VIII |
| - Conformity route | MDR annex II and III |

Other information (if applicable)

| | |
|--|---|
| - Common Specifications used for compliance | - |
| - Compliance to other legislations | EU 2016/425 |
| - 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/ 10648-06/E01-01. |
| - Standards used to assure compliance | Please see appendix II |

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 legislations mentioned "Compliance to other legislations".

This Declaration of Conformity is issued under the sole responsibility of the above mentioned manufacturer.

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| Name and Function: Jakob Lei Signature  | Place and date of issue Aabenraa, DK, 12-07-2023 |
| Abena, Egelund 35, DK-6200 Aabenraa | |

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| Template Responsible: JOHO | Created: JOHO | Approved: ULDA |
| File: Medical-Exam-Nitrile-Gloves-Classic" | Revision/Version: 1.5 | Date: 2022-11-02 |
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Appendix I, List of products

| Product Name | EMDN no | EMDN term description | Item no. | Basic UDI-DI |
|--|-----------|--|---|---------------------------|
| Classic Nitril Examination gloves powder free black colour, 200 pcs | T01020204 | Nitrile Examination / Treatment gloves | 290437-290441 | 570353800MeNF-001-06007CW |
| Classic Nitril Examination gloves powder free black colour, 100 pcs | T01020204 | Nitrile Examination / Treatment gloves | 290660-290664 | 570353800MeNF-001-06007CW |
| Classic sensitive Nitril Examination gloves powder free black colour, 100 pcs | T01020204 | Nitrile Examination / Treatment gloves | 290481-290485 | 570353800MeNF-001-06007CW |
| Classic Sensitive Nitrile Examination gloves powder free orange, pink, purple, green colour, 100 pcs | T01020204 | Nitrile Examination / Treatment gloves | 290710-290714 290720-290724 290730-290734 | 570353800MeNF-001-06010CK |

expand list accordingly

Appendix II, List of applicable standards used

| Standard title | No. and year |
|---|-------------------|
| 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 455-3:2015 |
| 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 |

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| Standard title | No. and year |
|---|-------------------|
| 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 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 |

expand list accordingly

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