



## Single EU Declaration of Conformity

### Legal Manufacturer

|  |  |   |
|--|--|---|
| - Name<br>- Address<br>- Phone / fax / email / webpage | ABENA A/S<br>Egelund 35<br>DK-6200 Aabenraa<br>Denmark | www.abena.com<br>Phone: +45 7431 1818<br>Fax: +45 7462 9737<br>Mail: info@abena.com |
| - Single Registration Number (SRN)                     | DK-MF-000002482  |   |

### Medical Device(s)


|   |   |
|---|---|
| - Intended Purpose  | 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. 5, MDR annex VIII   |
| - Conformity route  | MDR annex II and III                              |

### Other information (if applicable)

|  |  |
|--|--|
| - Common Specifications used for compliance  | -  |
| - Compliance to other legislations   | PPE Regulation EU 2016/425   |
| - Notified Body name and identification no. and description of the conformity assessment procedure performed | Notified body 2777 Satra Technology issued Module B PPE CE certificate 2777/24550-01/E07-01 and On-going conformity module D certificate |
| - Additional information   | -  |
| - 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.

|  |   |
|--|---|
| Name and Function:<br><b>Andreas K. Bisgaard, Category Manager</b><br>Signature<br> | Place and date of issue<br><br>Aabenraa, DK, 06-03-2026 |
| Abena, Egelund 35, DK-6200 Aabenraa  |   |

|   |                       |                  |
|---|-----------------------|------------------|
| Template Responsible: JOHO  | Created: JOHO         | Approved: ULDA   |
| File: medical-Exam-Nitrile-Glove-COATS 1999918931-35, 1000028951-55 | 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 COATS, powder free light blue colour, 100 pcs | T01020204 | Nitrile Examination / Treatment gloves | 1000028951-1000028955 | 571357100MeNF-001-06027A4 |
| Classic Nitril Examination gloves COATS, powder free light blue colour, 200 pcs | T01020204 | Nitrile Examination / Treatment gloves | 1999918931-1999918935 | 571357100MeNF-001-06027A4 |
|   |           |  |                       |                           |

### 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 455-2:2024     |
| Medical gloves for single use Requirements and testing for biological evaluation  | EN 455-3:2023     |
| Medical gloves for single use Requirements and testing for shelf life determination   | EN 455-4:2009     |
| Medical gloves for single use Requirements and testing for extractable chemical residues  | EN 455-5:2025     |
| Protective gloves against dangerous chemicals and micro-organisms Terminology and performance requirements for chemical risk                                | 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 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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