



## 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<br>Denmark | Fax: +45 7462 9737<br>Mail: info@abena.com |
| - Single Registration Number (SRN), if applicable | DK-MF-000002482             |                                            |

### Medical Device(s)

|                                                                              |                                                                                                                                      |
|------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|
| - Basic UDI-DI                                                               | 570353800MeNF-00I-06006CU                                                                                                            |
| - 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 | SATRA Technology Europe Limited<br>Bracetown Business Park<br>Clonee D15YN2P<br>Ireland                                                                                                                |
| - Additional information                                                                                     | EU Type Examination Module B and On-going conformity Module C2 performed by notified body 2777, SATRA Technology Europe Limited.<br>Issued EU Type Examination certificate number 2777/11521-01/E12-02 |
| - Standards used to assure compliance                                                                        | EU 2016/425, EN374-1:2016 Type B, EN374-4:2013, EN374-5:2016 Virus, EN16523-1:2015                                                                                                                     |

The above mentioned manufacturer hereby declares 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.

|                                                                                                                                                                                                                              |                                                                |
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| <b>Name and Function:</b><br><b>Khalid Elamri, Global Category Manager</b><br><b>Signature</b><br><br>Abena, Egelund 35, DK-6200 Aabenraa | <b>Place and date of issue</b><br><br>Aabenraa, DK, 11-05-2021 |
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|-------------------------------------------------|-----------------------|------------------|
| Template Responsible: JOHO                      | Created: JOHO         | Approved: ULDA   |
| File: Medical-Exam-Nitrile-Gloves-Classic Range | 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 Nitril Examination gloves<br>powder free blue colour<br>200 pcs and 100 pcs | 1999902086-1999902090<br>1999905271-1999905275 | -      | Protect patient and user<br>from cross-contamination. |

## Appendix II, List of applicable standards used

| Product Name                          | Standards used |
|---------------------------------------|----------------|
| Nitril Examination gloves powder free | EN 455-1:2002  |
| Nitril Examination gloves powder free | EN 455-2:2015  |
| Nitril Examination gloves powder free | EN 455-3:2015  |
| Nitril Examination gloves powder free | EN 455-4:2009  |
| 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 | EN420:2003     |

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