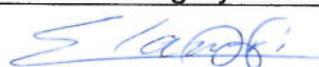


## Declaration of conformity Medical Devices, class I

|   |   |
|---|---|
| Legal Manufacturer:   | Abena A/S<br>including Abena International A/S<br>Egelund 35<br>DK - 6200 Aabenraa  |
| Conformity assessment procedure   | Annex VII of the Medical Devices Directive 93/42/EEC as amended by the Council Directive 2007/47/EEC.<br>Module B and Module D of PPE Regulation 2016/425 for category III. |
| Classification and harmonized standards   | <b>MDD Class I non sterile</b><br>EN 455 part 1,2,3,4<br>EN 374-1:2016<br>EN 374-2:2015<br>EN 16523-1:2015<br>EN 374-4:2013<br>EN 374-5:2016 VIRUS<br>EN 420: 2003+A1: 2009 |
| Product   | Excellent Nitrile Gloves, Powder and Accelerator-Free, Blue. Article no.<br>290405,290406,290407,290408,290409  |
| <p>This declaration of conformity is issued under the sole responsibility of the manufacturer:</p> <p>We, the legal manufacturer hereby declare that the above-mentioned product complies with the European Medical Device Directive 93/42/EEC as amended by the Council Directive 2007/47/EEC and its relevant transposition into all national laws of the member states into which we place the devices.</p> <p>EU Type Examination Module B performed by notified body 0321 SATRA Technology Centre, Wyndham Way, Telford Way, Kettering, Northamptonshire, NN16 8SD, United Kingdom, and issued the EU Type Examination certificate 0321/10013-02/E02-01. On-going conformity Module D by notified body 0120, SGS United Kingdom Limited Unit, 202B Worle Parkway Weston-Super-Mare, BS 22, United Kingdom.</p> |   |
| Signed in Aabenraa  | 05.12.2018  |
| Name and authority  | Khalid Elamri<br>Global Category Manager  |
| Signature   |   |

Date: 27-12-2013 Document responsible: Annika Matzen

Version: 06 Approved by: Annika Matzen

Updated by: AMA Doc. no. and name: 2.0.2S ENG Declaration of Conformity, Class I