



## Declaration of conformity Medical Devices, class I

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| 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 C2 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><b>PPE CAT III Type C</b><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  | Classic Examination Vinyl Gloves, Powder-Free, Transparent colour<br>Article no. 4431,4424,4425,4426,4430  |
| <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 and On-going conformity Module C2 performed by notified body 2777, SATRA Technology Europe Limited.<br/>Issued EU Type Examination certificate number 2777/11030-03/E04-01</p> |  |
| Signed in Aabenraa   | 15.09.2019   |
| Name and authority   | Khalid Elamri<br>Global Category Manager   |
| Signature  |  |