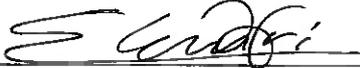


Declaration of conformity Medical Devices, class I

| | |
|---|--|
| Legal Manufacturer: | Abena A/S including Abena International A/S Egelund 35 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. Module B and Module C2 of PPE Regulation 2016/425 for category III. |
| Classification and harmonized standards | MDD Class I non sterile EN 455 part 1,2,3,4 PPE CAT III Type B EN 374-1:2016 EN 374-2:2015 EN 16523-1:2015 EN 374-4:2013 EN 374-5:2016 VIRUS EN 420: 2003+A1: 2009 |
| Product | Classic Examination Nitrile Gloves, Powder-Free, White and blue Colour. Article no. 290411,290412,290413,290414,290415 290417,290418,290419,290420,290421 290810,290811,290812,290813,290814 290820,290821,290822,290823,290824 290830,290831,290832,290833,290824 |
| <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, Bracetown Business Park, Clonee, D15YN2P Ireland.</p> <p>Issued the EU Type Examination certificate 2777/11578-01/E01-01</p> | |
| Signed in Aabenraa | 23.04.2019 |
| Name and authority | Khalid Elamri Global Category Manager |
| Signature |  |