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 D 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** 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	Excellent Nitrile Gloves, Powder and Accelerator-Free, Blue. 200 pcs Article no. 1000008823, 1000008822, 1000008821, 1000008820, 1000008819

This declaration of conformity is issued under the sole responsibility of the manufacturer:

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. 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.

Signed in Aabenraa	05.12.2018
Name and authority	Khalid Elamri Global Category Manager
Signature