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** EN ISO 374-1:2016 EN ISO 374-2 :2015 EN ISO 16523-1 :2015 EN ISO 374-4:2013 EN ISO 374-5:2016 VIRUS EN 420: 2003+A1: 2009
Product	Abena Antimicrobial Nitrile Gloves, Blue. Article no. 1000010125, 1000010126, 1000010127, 1000010128, 1000010129

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 and On-Going conformity Module C2 performed by notified body 0321 SATRA Technology Centre, Wyndham Way, Telford Way, Kettering, Northamptonshire, NN16 8SD, United Kingdom.
Issued the EU Type Examination certificate 0321/10473-02/E02-01.

Signed in Aabenraa	04.12.2018
Name and authority	Khalid Elamri Global Category Manager
Signature