




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 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. Article no. 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 Global Category Manager
Signature	

Date: 27-12-2013

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Updated by: AMA

Document responsible: Annika Matzen

Approved by: Annika Matzen

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Page 1 of 1