




## 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	<b>MDD Class I non sterile</b> EN 455 part 1,2,3,4 <b>PPE CAT III Type B</b> EN ISO 374-1:2016 K,P,T 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. 1000010201 - 1000010205 1000010125 - 1000010129
<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 and On-Going conformity Module C2 performed by notified body 2777 SATRA Technology Europe Limited, Bracetown Business Park, Clonee, D15YN2P Ireland. Issued the EU Type Examination certificate 2777/11080-02/E02-01</p>	
Signed in Aabenraa	24.09.2019
Name and authority	Khalid Elamri Global Category Manager
Signature	

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