

## 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	<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,T,P,O 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	Medical Examination Nitrile Gloves, Powder-Free, Blue and White colour. Article no. 290471,290472,290473,290474,290475 290610,290611,290612,290613,290614
<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 Limited, Wyndham Way, Telford Way, Kettering Northamptonshire, NN16 8SD United Kingdom. Issued the EU Type Examination certificate 0321/10015-02/E14-01. On-Going conformity Module D, performed by notified body 0120 SGS United Kingdom Limited, Unit 202B Worle Parkway, Weston-Super-Mare, BS22 6WA United Kingdom.</p>	
Signed in Aabenraa	25.04.2019
Name and authority	Khalid Elamri Global Category Manager
Signature	