

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 Type B EN ISO 374-1:2016 K,T,P 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 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 2777/10015-03/E06-01</p>	
Signed in Aabenraa	24.09.2019
Name and authority	Khalid Elamri Global Category Manager
Signature	