

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 374-1:2016 EN 374-2:2015 EN 16523-1:2015 K,P,T EN 374-4:2013 EN 374-5:2016 VIRUS EN 420: 2003+A1: 2009
Product	Classic Nitrile Gloves, Powder Free, Black colour. Classic Sensitive Nitrile Gloves, Powder Free, Black colour. Article no. 290437,290438,290439,290440,290441 290660,290661,290662,290663,290664
<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 module C2 conformity performed by notified body 2777 SATRA Technology Europe Limited, Bracetown Business Park, Clonee, D15YN2P Ireland. Issued the EU Type Examination certificate 2777/10648/E17-01.</p>	
Signed in Aabenraa	24.09.2019
Name and authority	Khalid Elamri Global Category Manager
Signature	