



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 PPE CAT III Type C EN 374-2:2015 EN 16523-1:2015 EN 374-4:2013 EN 374-5:2016 VIRUS EN 420: 2003+A1: 2009
Product	Classic Sensitive Nitrile Gloves, Powder-Free, Blue colour, Long cuff . Article no. 290466-290467-290468-290469-290470
<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 Class I 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 under self-certification.</p> <p>EU Type Examination Module B and On-going conformity Module D under personal protective equipment is performed by notified body 0598 SGS Fimko OY., P.O. Box 30 Särkiniementie 3, 00211 Helsinki, Finland. Issued the EU Type Examination certificate FI19/963856 under Regulation (EU) 2016/425.</p>	
Signed in Aabenraa	24.08.2019
Name and authority	Khalid Elamri Global Category Manager
Signature	