

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	MDD Class I non sterile EN 455 part 1,2,3,4 PPE CAT III Type B EN 374-1:2016 J,K,P,T EN 374-2:2015 EN 16523-1:2015 EN 374-4:2013 EN 374-5:2016 VIRUS EN 420: 2003+A1: 2009
Product	Excellent Examination Nitrile Gloves, Powder-Free, White and Blue Colour. Article no. 3940,3941,3942,3943,3944 290423,3958,3959,3960,3961,3945 290425,290426,290427,290428,290429 290431,3924,3925,3926,3927
<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.</p> <p>Issued the EU Type Examination certificate 2777/11513-01/E01-01</p>	
Signed in Aabenraa	25.04.2019
Name and authority	Khalid Elamri Global Category Manager
Signature	