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 C** EN 374-1:2016 EN 374-2:2015 EN 16523-1:2015 EN 374-4:2013 EN 374-5:2016 VIRUS EN 420: 2003+A1: 2009
Products	Classic Sensitive Examination Nitrile Gloves, Powder-Free, Blue, White, Black, Orange, Purple, Pink, Green. Article no. 290495,290496,290497,290498,290499 290417,290418,290419,290420,290421 290411,290412,290413,290414,290415 290471,290472,290473,290474,290475 290610,290611,290612,290613,290614 290481,290482,290483,290484,290485 290710,290711,290712,290713,290714 290720,290721,290722,290723,290724 290730,290731,290732,290733,290734 290740,290741,290742,290743,290744
This declaration of conformity is issued under the sole responsibility of the manufacturer: 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. EU Type Examination Module B performed by notified body CE0493, Centexbel, Technologiepark 7,BE 9052 Gent, Belgium and issued the EU Type Examination certificate 045/2019/0022.02. On-going conformity Module D by notified body 0598, SGS Fimko Oy, P.O. Box 30 (Särkiniementie 3) 00211 Helsinki, Finland.	
Signed in Aabenraa	12.11.2019
Name and authority	Khalid Elamri Global Product Manager
Signature	