Declaration of conformity
Medical Devices, class I

Legal Manufacturer:	Abena A/S including Abena International A/S Egelund 35 DK - 6200 Aabenraa Distributor: WM SUPPLIES, bvba, B-8520 Kuurne, Belgium
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 C** EN ISO 374-1:2016 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, Blue colour. Advance Clinic design Article no. 1000006242, 1000006243, 1000006244, 1000006245, 1000006246

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 and On-Going conformity Module C2 performed by notified body 2777 SATRA Technology Europa Limited, Bracetown Business Park, Clonee. D15YN2P, Ireland. Issued the EU Type Examination certificate 2777/11578-01/E03-01.

Signed in Aabenraa	25.04.2019
Name and authority	Khalid Elamri Global Category Manager
Signature