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 ISO 374-1:2016 K,P.T 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 Latex Gloves, Powder-Free, Natural colour. Article no. 290211,290212,290213,290214,290215

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 2777/11080-02/E01-01.

Signed in Aabenraa	24.09.2019
Name and authority	Khalid Elamri Global Category Manager
Signature