



Declaration of conformity Medical Devices, class I

Legal Manufacturer:	Abena A/S including Abena International A/S Egelund 35 DK - 6200 Aabenraa Distributor: Sligro B.V., Corridor 11, NL 4566 RB Veghel
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 (EU) 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 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
Products	Felicia Vinyl Gloves, Powdered Transparent color Sizes: Small, Medium, Large, X-large
<p>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.</p> <p>EU Type Examination Module B and On-going conformity Module C2 performed by notified body 2777 SATRA Technology Europe Ltd., Bracetown Business Park, Clonee, Dublin, D15 YN2P Ireland. Issued the EU Type Examination certificate 2777/11331-02/E14-01.</p>	
Signed in Aabenraa	25.10.2019
Name and authority	Khalid Elamri Global Category Manager
Signature	