

DECLARATION OF CONFORMITY

Legal Manufacturer:	Fredman Professional Kitchen Oy Vänrikinkuja 3 02600 Espoo Finland
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 EN ISO 374-1:2016 EN 374-4:2013 EN ISO 374-5:2016 EN 420: 2003+A1: 2009
Product	Vinyl Medical Examination Gloves, Powder-Free Sizes: Small, Medium, Large Article no. 9061-9063
<p>This declaration of conformity is issued under the sole responsibility of the manufacturer:</p> <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. 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 xxxxxx</p>	
Signed in Espoo	August 03, 2020
Name and authority	Marju Vroman Director, People and Sustainability Programs
Signature	