

Declaration of Conformity

Medical Devices, class I

Legal Manufacturer:	
Conformity assessment procedure	Annex VII of the Medical Devices Directive 93/42/EEC as amended by the Council Directive 2007/47/EEC.
Classification and Harmonized standards	MDD Class I non sterile EN 455 part 1, 2, 3, 4 PPE CAT III EN 374-1:2016 EN 374-2:2015 EN 16523-1:2015 EN 374-4:2013 EN 374-5:2016 VIRUS EN 420:2003+AI:2009
Product	Nitrile and Latex Examination Powder Free Gloves
<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 93/42/EEC as amended by the Council Directive 2007/47/EEC and its relevant transportation into all national laws of the member states into which we place the devices.</p> <p>EU Type Examination Module B performed by notified body 2777 SATRA Technology Europe Limited, Bracetown Business Park, Clonee, D15YN2P Ireland and issued the EU Type Examination certificate 2777/11793-01/E00-00 and 2777/11792-01/E00-00. On-going conformity EU MDR-Regulation (EU) 2017/745 by notified body BSI Assurance UK Limited, 389 Chiswick High Road, London W4 4AL, UK.</p> <p>EU Representative: S.B Pharma GmbH, Max-Planck-Str.39a, 50858 Koln, Germany. Tel: (+49) 2234-988-15-21 / Fax: (+49) 2234-988-15-23 Contact person: Dr.Sina Seifi Noferesti E-mail: sina.seifi(Ssb-Dharma.com)</p>	
Signed Date	12-May-2020
Name and Authority	Ganesh Subramaniam & Group QA/RA Manager