

DECLARATION OF CONFORMITYManufacturer

Lalan Rubbers (Pvt) Ltd

No. 95/B, Zone A, Export Processing Zone, Biyagama, Malwana, Sri Lanka

Declares that the product described hereafter

LE001 - Latex examination pre powder gloves-White, Green, Yellow, Pink, Purple & Blue ;

are in conformity with the provisions of Module B and Module C2 of the Regulation (EU) 2016/425 Personal Protective Equipment and with the national standard transposing harmonized standard (s)

- EN 420:2003+A1:2009
- EN ISO 374-2:2014
- EN16523-1:2015
- EN 374-4:2013
- EN ISO 374-5:2016

Product designation- LE 001**Latex examination powdered gloves**

S,M,L,XL

EN ISO 374-1: 2016+A1:2018 Type C

CE2777



ENISO374-5:2016



Manufacturer : Lalan Rubbers (Pvt)Ltd , No.95/B, Zone A,
Export Processing Zone, Biyagama,
Malwana, Sri Lanka

issued by;

SATRA Technology Europe Ltd.,Bracetown Business Park , Clonee, D15 YN2P, Ireland.

Notified Body No: 2777.

is subject to the procedure set out in Module C2 of Regulation (EU) 2016/425 Personal Protective Equipment under the supervision of the notified body, SATRA Technology Europe Ltd.,Bracetown Business Park , Clonee, D15 YN2P, Ireland.

Authorized representative

Bastide le confort medical

Cs 28 219

30942 nimes cedex 9, France

And,

are in conformity with the provisions of the Council Directive 93/42/EEC (modified by 2007/47/EC) for medical devices as Class I device and with the national standard transposing harmonized standard (s)

- EN 455-1:2000
- EN 455-2:2015
- EN 455-3:2015

Device Classification: Council Directive 93/42/EEC, Annex IX, Rule 5- Class I

Conformity Assessment Route: Manufacturer makes written declaration of conformity according to Council Directive 93/42/EEC, Annex VII and affixes CE marking. Manufacturer draws up the technical documentation.

Intended use: These gloves are intended to be worn by medical examination and therapeutic personnel to protect from contaminations.



LALAN Rubbers (Pvt) Ltd
No. 95/B, Zone A, Export Processing Zone,
Biyagama, Malwana,
Sri Lanka.

K. Renuka Priyangi.

Head of Quality Assurance,

Place - Lalan Rubbers (Pvt) Ltd – Head Office