PRIMUS GLOVES PVT LIM

Plot No.14-A Cochin Special Economic Zone, Kakkanad, Cochin - 682 037, Kerala, INDIA

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Declaration of Conformity

Product name

Sterile Latex Surgical Gloves Powdered & Powder free

Model/Type

Primus Gloves Private Limited

Name Address Plot No 14-A, Cochin Special Economic Zone, Kakkanad

Cochin-37, Kerala

Country

India

Representative

Authorized Representative in Europe

Name Address Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands

Country: tel: fax:

+31 (0)70 345 8570 +31 (0)70 346 7299

Classification:

Class IIa - Rule 6, Annex IX, MDD 93/42/EEC as amended by

Directive 2007/47/EC

Conformity Route Assessment:

Annex V of the MDD 93/42/EEC Council Directive as amended

by Directive 2007/47/EC

Primus Gloves Private Limited declares that the above mentioned product meet the provision of the Council Directive MDD 93/42/EEC as amended by Directive 2007/47/EC for Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

relail

Notified Body:

DNV GL Nemko Presafe AS CE 2460

(EC) Certificate #:

11491-2017-CE-IND-NA-PS Rev 2.0

Place and Date:

Kakkanad

29.07.21

Signature

Name

Jose Paul M

Position

Director Technical & RA

