EC CERTIFICATE
Production Quality Assurance

Certificate no.:
11491-2017-CE-IND-NA-PS

Initial certification date:
16 November 2017

Valid Until:
26 May 2024

This is to certify that the management system of
Primus Gloves Private Limited
Plot No.14-A, Cochin Special Economic Zone, Kakkanad,682 037,Kochi,Kerala,India

For design, production and final product inspection/testing of:
STERILE SURGICAL AND EXAMINATION GLOVES

has been assessed and found to comply with respect to:
the conformity assessment procedure described in Annex V of Council Directive 93/42/EEC on Medical Devices, as amended

Place and date:
Høvik, 07 May 2021

For the issuing office:
DNV Product Assurance AS - Notified Body 2460
Veritasveien 3, 1363 Høvik, Norway

ALESSANDRA RINNA
Assessor

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

Jurisdiction
Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate History		
Revision	**Description**	**Issued Date**
0.0	Supersedes DNV GL (NB 0434) certificate No. 102349-2011-CEIND-NA Rev.4.0 following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460).	16 November 2017
1.0	Brand Addition (in Bold)	25 March 2020
2.0	Recertification	07 May 2021

Products covered by this Certificate:		
Product Description	**Product Name**	**Class**
Sterile Latex Surgical Gloves Powdered	Latex Surgical Gloves (Regular) – Primus*, Primus, Abcon, Sensimedical, Luxor, Primus50, Healthcare Plus, Novicare, Protac, Protex, Krivicare, Maxens, Protac, Latex Surgical Gloves (High Risk) – Primus	IIa
Sterile Latex Surgical Gloves Powder Free	Latex Surgical Gloves (Regular) – Primus*, Primus *PF, Primus*PF polymer Coated, Luxor, Novicare, Primus *PF, Euromedis, KBM, Protac, Primus Vacupack, Krivicare, Protex, Maxens	IIa
Sterile Latex Orthopaedic Surgical Gloves Powdered	Latex Orthopaedic Surgical Gloves – Primus Orthopaedic	IIa
Sterile Latex Orthopaedic Surgical Gloves Powder Free	Latex Orthopaedic Surgical Gloves – Primus, Primus Plus 26 Mil, Protex	IIa
Sterile Latex Ophthalmic Surgical Gloves – Powder Free	Latex Ophthalmic Surgical Gloves – Primus Micro, Primus Ophthalmic	IIa
Sterile Latex Examination Gloves Powdered	Latex Examination Gloves – Primus, Primus*, Primus*PE, Primus Exam Single, Luxor, Primus Exam, Torval, Primus*SE, Protex	Is
Sterile Latex	Latex Examination Gloves – Primus,	Is

Examination Gloves Powder Free	Primus*, Primus*PEPF, Primus Exam Single, Primus*SEPF	
Sterile Latex Long Cuff Examination Gloves Powdered	Latex Examination Gloves Longcuff – Primus	Is
Sterile Latex Long Cuff Examination Gloves Powder Free	Latex Examination Gloves Longcuff – Primus	Is
Sterile Nitrile Surgical Gloves Powder Free	Nitrile Surgical Gloves Powder Free – Primus	IIa
Sterile Nitrile Examination Gloves Powder Free	Nitrile Examination Gloves – Primus	Is
Sterile Latex Long Cuff Surgical Gloves Powdered	Long Cuff Surgical Gloves Powdered – Surgilac, Primus, Latex Gynaecological Gloves Powdered – HM Health care	IIa
Sterile Latex Long Cuff Surgical Gloves Powder Free	Long Cuff Surgical Gloves Powder Free – Surgilac, Primus, Sterix, Latex Surgical Gloves (Long Cuff) – Primus Gynaecological	IIa

Sites covered by this certificate	
Site Name	**Site Address**
Primus Gloves Private Limited	Plot No.14-A, Cochin Special Economic Zone, Kakkanad,Kochi - 682 037, Kerala, India

EU Representative
EMERGO EUROPE, Prinsessegracht 20, 2514 AP The Hague, The Netherlands

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.