

APPENDIX TO EC CERTIFICATE

Appendix to Certificate no.:

Valid Until:

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

26 May 2024

This is an Appendix issued to EC Certificate issued for manufacturer:
Primus Gloves Private Limited

originally issued in compliance with:
the Council Directive 93/42/EEC on Medical Devices, as amended

Based on assessment performed, the following changes to the certification has been accepted as compliance with Council Directive 93/42/EEC on Medical Devices has been established.

A device already covered by the certification is placed on the market under an additional name or Identifier.

Products covered by this Certificate (replaces information on certificate):		
11491-2017-CE-IND-NA-PS Rev. 2.0		
Product Description	Product Name/ Brand	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, Precinium	Ila
Sterile Latex Long Cuff Surgical Gloves Powdered	Long Cuff Surgical Gloves Powdered – Surgilac, Primus, Latex Gynaecological Gloves Powdered – HM Health care, Protac	Ila
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 Primus, Precinium, Protac Polymer coated	Ila

Place and date:
Høvik, 19 July 2021



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

Hazem Tinawi
 Technical Reviewer

Sterile Latex Long Cuff Surgical Gloves Powder free	Long Cuff Surgical Gloves Powder Free – Surgilac, Primus, Sterix, Latex Surgical Gloves (Long Cuff) – Primus Gynaecological Primus, Protac, Euromedis	Ila
Sterile Latex Examination Gloves Powder free	Latex Examination Gloves – Primus, Primus*, Primus*PEPF, Primus Exam Single, Primus*SEPF, Protac	Is
Sterile Latex Long Cuff Examination Gloves Powdered	Latex Examination Gloves Longcuff – Primus, Protac	Is
Sterile Latex Long Cuff Examination Gloves Powder free	Latex Examination Gloves Longcuff – Primus, Protac	Is
Sterile Latex Orthopaedic Surgical Gloves Powdered	Latex Orthopaedic Surgical Gloves – Primus Orthopaedic	Ila
Sterile Latex Orthopaedic Surgical Gloves Powder Free	Latex Orthopaedic Surgical Gloves – Primus, Primus Plus 26 Mil, Protex	Ila
Sterile Latex Ophthalmic Surgical Gloves – Powder Free	Latex Ophthalmic Surgical Gloves – Primus Micro, Primus Ophthalmic	Ila
Sterile Latex Examination Gloves Powdered	Latex Examination Gloves – Primus, Primus*, Primus*PE, Primus Exam Single, Luxor, Primus Exam, Torval, Primus*SE, Protex	Is
Sterile Nitrile Surgical Gloves Powder Free	Nitrile Surgical Gloves Powder Free – Primus	Ila
Sterile Nitrile Examination Gloves Powder Free	Nitrile Examination Gloves – Primus	Is

Appendix History -

Revision	Description	Issued Date
0.0	Brand addition in bold.	19 July 2021