



DET NORSKE VERITAS

EC CERTIFICATE – PRODUCTION QUALITY ASSURANCE

Certificate No. 102349-2011-CE-IND Rev. 4.0

This Certificate consists of 4 pages

This is to certify that the Quality Management System of

Primus Gloves Private Limited

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

for production and final product inspection/testing of

Sterile Surgical and Examination Gloves

has been assessed with respect to

the conformity assessment procedure described in Article 11.2.b and Annex V (Module D1)
of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

Further details are given overleaf

Place and date:

Høvik, 10 December 2016

This Certificate is valid until:

25 September 2021

For DNV GL BUSINESS ASSURANCE
NORWAY AS



Tone Kolpus
Certification Manager

Notified Body No.:
0434

Cathrine Wisbech
Technical Reviewer

This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info

Notice: The certificate is subject to terms and conditions overleaf. Any significant changes in design or construction may render this certificate invalid.

If any person suffers loss or damage which is proved to have been caused by any negligent act or omission of Det Norske Veritas, then Det Norske Veritas shall pay compensation to such person for his proved direct loss or damage. However, the compensation shall not exceed an amount equal to ten times the fee charged for the service in question, provided that the maximum compensation shall never exceed USD 300.000. In this provision "Det Norske Veritas" shall mean the Foundation Det Norske Veritas as well as all its subsidiaries, directors, officers, employees, agents and any other acting on behalf of Det Norske Veritas.



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 Project No.: PRJC-249019-2010-PRC-IND

Jurisdiction

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

Certificate history

Revision	Description	Issue Date
	Original Certificate 2006-OSL-MDD-0357	2006-09-25
1.0	Recertification	2011-09-25
2.0	New brand name added (in bold)	2013-02-14
3.0	New brand name added (in bold)	2014-11-11
4.0	Re-certification	2016-12-09

Products covered by this Certificate

The complete list of devices is filed with the Notified Body.

EU Representative

EMERGO EUROPE, MOLENSTRAAT 15, 2513 BH, THE HAGUE – THE NETHERLAND

Product:	Type/Model	Class
Sterile Latex Surgical Gloves Powdered	Latex Surgical Gloves (Regular) – Primus*, Primus, Abcon, Sensimedical, Luxor, Primus50, Healthcare Plus Latex Surgical Gloves (High Risk) – Primus* Latex Surgical Gloves (regular) – Novicare, Protac	IIa
Sterile Latex Surgical Gloves Powder free	Latex Surgical Gloves (Regular) – Primus*, Primus *PF, Primus*PF polymer coated, Luxor, Primus, Latex Surgical Gloves (Regular) – Novicare, Primus *PF, Euromedis	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	IIa



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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 Latex, Primus Exam, Torval, Primus* SE	Is
Sterile Latex Examination Gloves Powder free	Latex Examination Gloves –Primus, Primus*, Primus Exam Singles, Primus* PEPF, Primus* SEPF	Is
Sterile Latex Long Cuff Examination Gloves Powdered	Latex Examination Gloves Long cuff -Primus	Is
Sterile Latex Long Cuff Examination Gloves Powder free	Latex Examination Gloves Long cuff -Primus	Is
Sterile Nitrile Surgical Gloves Powdered	Nitrile Surgical Gloves Powdered –Primus	IIa
Sterile Nitrile Surgical Gloves Powder free	Nitrile Surgical Gloves –Primus	IIa
Sterile Vinyl Examination Gloves Powdered	Vinyl Examination Gloves – Primus, Primus* PV, Primus* SV, Luxor Vinyl	Is
Sterile Vinyl Examination Gloves Powder free	Vinyl Examination Gloves – Primus, Primus* PVPF, Primus* SVPF,	Is
Sterile Nitrile Examination Gloves Powdered	Nitrile Examination Gloves –Primus	Is
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 Latex Surgical Gloves (Long Cuff) Primus Gynaecological	IIa

Sites covered by this certificate



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Site Name	Address
Primus Gloves Private Limited	Plot No. 14-A, Cochin Special Economic Zone, Kakkanad, Pin Code-682 037, Kochi, Kerala, India

EC Representative	Address
EMERGO EUROPE	MOLENSTRAAT 15 2513 BH THE HAGUE THE NETHERLANDS PH:+31(0) 703458570

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 local DNV Office of any intended updating of the quality system and DNV 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 DNV 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 of DNV.

END OF CERTIFICATE