EC Certificate
Production Quality Assurance

Certificate No.:	Project No.:	Valid Until:
11491-2017-CE-IND-NA-PS Rev. 0.0	**PRJC-249019-2010-PRC-IND**	**25 September 2021**

This is to certify that the quality system of:

For distribution 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 of the product(s) and conditions for certification are given overleaf.

Place and Date:
The Hague, 16 November 2017

For:
DNV GL NEMKO PRESAFE AS

Alessandra Rinna

PROD 021
Notified Body No.: 2460

The Certificate has been digitally signed.

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Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted by the Dutch Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Supersedes DNV GL (NB 0434) certificate No. 102349-2011-CE-IND-NA Rev.4.0 following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460).	2017-11-16

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 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	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
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	Is
Sterile Latex Examination Gloves Powder Free	Latex Examination Gloves – Primus, Primus*, Primus*PEPF, Primus Exam Single, Primus*SEPF	Is
Sterile Latex Long Cuff	Latex Examination Gloves Longcuff – Primus	Is

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Examination Gloves Powdered		
Sterile Latex Long Cuff Examination Gloves Powder Free	Latex Examination Gloves Longcuff – 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

The complete list of devices is filed with the Notified Body

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 Presafe of any intended updating of the quality system and Presafe 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. Presafe 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 Presafe.

End of Certificate