

DECLARATION OF CONFORMITY

MEDICAL DEVICE DIRECTIVE 93/42/EEC

PERSONAL PROTECTIVE EQUIPMENT DIRECTIVE 89/686/EEC

Legal Manufacturer:

Semperit Investments Asia Pte Ltd
8 Jurong Town Hall Road
#29-03/04/05/06 JTC Summit
Singapore 609434
<http://www.sempermed.com>
E-mail: sempermed@semperitgroup.com

Authorized representative in the EC:

Semperit Technische Produkte Gesellschaft m.b.H
Modcenterstraße 22
1030 Vienna, Austria

This certificate is valid for the following product:

Non-sterile examination and protective glove for single use

Classification: class I according to MD Directive; category III according to PPE Directive

semperguard latex powdered

Sizes	X-Small	Small	Medium	Large	X-Large
Art. No.	813987021	813987023	813987025	813987027	813987029
Alt. Art. No.	3000001414	3000001415	3000001416	3000001417	3000001418

We hereby declare under sole responsibility that the CE marked product described above conforms to the essential requirements (Annex I) of the directive for medical devices 93/42/EEC.

The conformity assessment is based on Annex VII. Classification according to rule 5, Annex IX.

Applied standards: EN 455-1:2000, EN 455-2:2009+A2:2013 & EN 455-2:2015, EN 455-3:2006 & EN 455-3:2015, EN 455-4:2009, ISO 10993-1:2013, EN ISO 15223-1:2017, EN 1041:2013, EN ISO 14971:2013, DIN ISO 2859-1:2014, , EN ISO 13485:2016

We hereby certify that the CE 0321 marked product described above conforms with the applicable provisions of the directive for personal protective equipment 89/686/EEC and is identical to the personal protective equipment which is the subject of the EC certificate of conformity No. 8508 Issue 1 issued by

SATRA Technology Centre, Wyndham way, Telford Way, Kettering, Northamptonshire, NN16 8SD, United Kingdom, ID No. 0321

and is subject to the procedure set out in article 11A of Directive 89/686/EEC under the supervision of

SATRA Technology Centre, Wyndham way, Telford Way, Kettering, Northamptonshire, NN16 8SD, United Kingdom, ID No. 0321

Applied standards: EN 420:2003+A1:2009, EN 374-1:2003, EN 374-2:2003, EN 374-3:2003, EN 388:2003


Andreas Wöss
Director


Released by: Johann Glantschnig
Regulatory Affairs Manager Sempermed

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