sempermed®
A MEMBER OF THE SEMPERIT-GROUP

DECLARATION OF CONFORMITY

MEDICAL DEVICE DIRECTIVE 93/42/EEC

PERSONAL PROTECTIVE EQUIPMENT DIRECTIVE 89/686/EEC

Legal Manufacturer:

Semperit Investments Asia Pte Ltd
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#29-03/04/05/06 JTC Summit
Singapore 609434
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Authorized representative in the EC:

Semperit Technische Produkte Gesellschaft m.b.H
Modecenterstraße 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

sempercare soft

Sizes	X-Small	Small	Medium	Large	X-Large
Art. No.	826768531	826768533	826768535	826768537	826768539
Alt. Art. No.	3000002866	3000002867	3000002868	3000002869	3000002870

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. 7135 Issue 2 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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