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
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
Modecenterstraße 22
1030 Vienna, Austria

This certificate is valid for the following product:

Sterile surgical and protective glove for single use
Classification: class IIa according to MD Directive; category III according to PPE Directive

sempermed syntegra IR

Sizes	5,5	6	6,5	7	7,5	8	8,5	9
Art. No.	827056521	827056601	827056621	827056701	827056721	827056801	827056821	827056901

We hereby declare under sole responsibility that the CE 0123 marked product described above conforms to the essential requirements (Annex I) of the directive for medical devices 93/42/EEC.

Declaration based on Annex II excluding (4). Classification according rule 6, appendix 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, EN ISO 11137-1:2015, ISO 10993-1:2013, EN ISO 15223-1:2017, EN 556-1:2006, EN ISO 11607:2015, EN 1041:2013, EN ISO 14971:2013, EN ISO 2859-1:2014, DIN 7716:1982, ISO 2230:2002, ISO 10282:2014, EN ISO 13485:2016
Notified Body: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EC Certificate No.: G1 16 1288308 013

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. 8011 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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