sempermed®
A MEMBER OF THE SEMPERIT-GROUP

DECLARATION OF CONFORMITY

MEDICAL DEVICE DIRECTIVE 93/42/EEC
PERSONAL PROTECTIVE EQUIPMENT REGULATION (EU) 2016/425

Legal Manufacturer

Semperit Investments Asia Pte. Ltd.
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#29-03 to 06 The JTC Summit,
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www.sempermed.com
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Authorized representative in the EU

Semperit Technische Produkte GmbH
Modecenterstraße 22
1030 Vienna, Austria

This certificate is valid for the following product:

Sterile examination and protective glove for single use
Classification: Class Is according to MD Directive 93/42/EEC
Category III according to PPE Regulation (EU) 2016/425

sempercare nitrile sterile

Sizes	X-Small	Small	Medium	Large	X-Large
Article codes		826753627	826753727	826753827	826753927
Article codes		3000002058	3000002059	3000002060	3000011250

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.

The conformity assessment is based on Annex V. Classification according rule 5, appendix IX.

Applied standards: EN 455-1:2000, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN 556-1:2001/ AC:2006, ISO 11137-1:2006 AMD 2:2018, ISO 11607-1:2019, ISO 13485:2016, EN ISO 14971:2013, ISO 15223-1:2016, ISO 10993-1:2018, ISO 2230:2002, DIN 7716:1982, ISO 10282:2014, ISO 2859-1:1999 AMD 1:2011, IEC 62366-1:2015/COR 1:2016

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EC Certificate No.: G2S 18 03 88308 017

We hereby declare under sole responsibility that the CE marked product described above conforms with the applicable provisions of Regulation (EU) 2016/425 on personal protective equipment and is identical to the personal protective equipment which is subject to EU Type Examination Certificate No. 2777/11461-01/E05-01 issued by:
SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland
The products are subject to the procedure set out in Annex VII (Module C2) of Regulation (EU) 2016/425 under the supervision of
SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Applied standards: EN 420:2003+A1:2009, EN ISO 374-1:2016+A1:2018, EN 374-2:2014, EN 16523-1:2015, EN 374-4:2013, EN ISO 374-5:2016, EN421:2010

Andreas Wöss
Director

Released by: Christian Rohrbach

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This signed document is valid for all translations attached.