sempermed®
A MEMBER OF THE SEMPERIT-GROUP

DECLARATION OF CONFORMITY

MEDICAL DEVICE DIRECTIVE 93/42/EEC

Legal Manufacturer

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

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SRN: AT-AR-000000735

This certificate is valid for the following product:

Sterile surgical glove for single use
Classification: Class IIa according to MD Directive 93/42/EEC

sempermed supreme (USA)

Sizes	X-Small	Small	Medium	Large	X-Large
Article codes	822751527	822751607	822751707	822751807	822751907
	3000006119	3000006120	3000006122	3000006124	3000006126

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: ASTM D3577-19, ASTM F1671/F1671M-13, EN ISO 20417:2021, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2014, ISO 2230:2002

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EC Certificate No.: G1 088308 0018 Rev. 00

Andreas Wöss
Director

Released by: Christian Rohrbach

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This signed document is valid for all translations attached.