

DECLARATION OF CONFORMITY

MEDICAL DEVICE REGULATION (EU) 2017/745
 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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 sempermed@semperitgroup.com
 SRN: SG-MF-000001645

Authorized representative in the EU

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 sempermed@semperitgroup.com
 SRN: AT-AR-000000735

This certificate is valid for the following product:

Non-sterile examination and protective glove for single use

Classification: Class I according to MD Regulation (EU) 2017/745
 Category III according to PPE Regulation (EU) 2016/425

Basic UDI-DI: 9001570L*F-050NA-N-3LC

sempermed edition (APAC)

Sizes	X-Small	Small	Medium	Large	X-Large
Article codes	3000014281	3000014282	3000014283	3000014285	3000014286

We hereby declare under sole responsibility that the CE marked product described above conforms to the requirements of the regulation for medical devices (EU) 2017/745.

Declaration based on Annex IV. Classification according to rule 5, Annex VIII. The conformity assessment is based on Annex II.

Applied standards: ASTM D3578-19, ASTM D6319-19 or ASTM D5250-19, 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 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, 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, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006

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. VN620 143495 issued by:

**OETI - Institut fuer Oekologie, Technik und Innovation GmbH,
 Siebenhirtenstrasse 12A, Objekt 8, 1230 Vienna, Austria**

The products are subject to the procedure set out in Annex VII (Module C2) of Regulation (EU) 2016/425 under the supervision of

**OETI - Institut fuer Oekologie, Technik und Innovation GmbH,
 Siebenhirtenstrasse 12A, Objekt 8, 1230 Vienna, Austria**

Applied standards: EN 420:2003+A1:2009, ISO 374-1:2016/AMD 1:2018, EN 374-2:2014, EN 16523-1:2015+A1:2018, EN 374-4:2013, EN ISO 374-5:2016, ISO 2859-1:1999 AMD 1:2011



Andreas Wöss
 Director



Released by: Christian Rohrbach

This signed document is valid for all translations attached.

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