

DECLARATION OF CONFORMITY

MEDICAL DEVICE REGULATION (EU) 2017/745
PERSONAL PROTECTIVE EQUIPMENT REGULATION (EU) 2016/425

Legal Manufacturer

Semperit Investments Asia Pte. Ltd.
8 Jurong Town Hall Road,
#29-03 to 06 The JTC Summit,
Singapore 609434, Singapore
sempermed@semperitgroup.com
SRN: SG-MF-000001645

Authorized representative in the EU

Semperit Technische Produkte Gesellschaft m.b.H.
Triester Bundesstraße 26, 2632 Wimpassing, Austria
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

sempercare edition

| Sizes | X-Small | Small | Medium | Large | X-Large |
|---------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Article codes | 823781731 3000001779 | 823781733 3000001780 | 823781735 3000001781 | 823781737 3000001782 | 823781739 3000001783 |

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

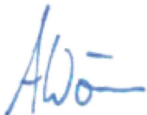
We hereby declare under sole responsibility that the CE marked product described above conforms with the applicable provisions of Regulation (EU) 2016/425 on personal protective equipment and is identical to the personal protective equipment which is subject to EU Type Examination Certificate No. VN620 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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IZJAVA O SKLADNOSTI

UREDBA O MEDICINSKIH PRIPOMOČKIH (EU) 2017/745/EGS
UREDBA (EU) 2016/425 ZA OSEBNO VAROVALNO OPREMO

Proizvajalec

Semperit Investments Asia Pte. Ltd.
8 Jurong Town Hall Road,
#29-03 to 06 The JTC Summit,
Singapore 609434, Singapore
sempermed@semperitgroup.com
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Pooblaščen zastopnik EU

Semperit Technische Produkte Gesellschaft m.b.H.
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SRN: AT-AR-000000735

To potrtilo velja za naslednje izdelke:

Nesterilne zaščitne rokavice in rokavice za preglede za enkratno uporabo

Klasifikacija: Razred I v skladu z Uredbo o medicinskih pripomočkih (EU) 2017/745/EGS
Kategorija III v skladu z Uredbo OVO (EU) 2016/425

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

sempercare edition

| Velikosti | X-Small | Small | Medium | Large | X-Large |
|-------------------|-----------|-----------|-----------|-----------|-----------|
| Številke izdelkov | 823781731 | 823781733 | 823781735 | 823781737 | 823781739 |

S to izključno odgovornostjo izjavljamo, da so izdelki z oznako CE v skladu z zahtevami Uredbe za medicinske pripomočke (EU) 2017/745.

Izjava na podlagi Priloge IV. Razvrstitev v skladu s Prilogo VIII k Pravilniku 5. Ocenjevanje skladnosti temelji na Prilogi II.

Uporabljeni standardi: 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

S to izključno odgovornostjo izjavljamo, da so zgoraj navedeni izdelki z oznako CE v skladu z bistvenimi zahtevami Uredbe (EU) 2016/425 za osebno varovalno opremo in so predmet certifikata ES o pregledu tipa št. VN620 143495 izdano :

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

Izdelki so predmet postopka v skladu s Prilogo VII (modul C2) uredbe pod nadzorom

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

Uporabljeni standardi: 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

Izdano dne: Singapore, 2022-01-10

Veljavno do: 2024-01-09