

EU 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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SRN: SG-MF-000001645

Authorized representative in the EU

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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: 9001570N*F-030VB-N-3RB

sempercure nitrile skin² (TD / AQL 1.0)

Sizes	X-Small	Small	Medium	Large	X-Large
Article codes	3000012742	3000012743	3000012744	3000012745	3000012746

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. 2777/11466-03/E02-01 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 ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN ISO 374-4:2019, EN ISO 374-5:2016, ISO 2859-1:1999 AMD 1:2011



Andreas Wöss
 Sr Vice President Sales


 Released by: Christian Rohrbach

This signed document is valid for all translations attached.

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