

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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Singapore 609434, Singapore
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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:

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-047OB-N-3SS

sempercare nitrile (IVF)

Sizes	X-Small	Small	Medium	Large	X-Large
Article codes	826781631	826781633	826781635	826781637	826781639
Article codes		3000007645	3000007646	3000007647	3000007648

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 rule 5, appendix VIII.

Applied standards: EN 455-1:2000, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, ISO 13485:2016, EN ISO 14971:2013, ISO 15223-1:2016, ISO 10993-1:2018, ISO 2859-1:1999 AMD 1:2011, IEC 62366-1:2015 / COR 1:2016

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/E01-01 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, 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, EN 421:2010


Andreas Wöss
Director


Released by: Christian Rohrbach

This signed document is valid for all translations attached.

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