

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: 9001570L*F-050NA-N-3LC

sempercure edition (IVF)

Sizes	X-Small	Small	Medium	Large	X-Large
Article codes	823781731	823781733	823781735	823781737	823781739

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. VN620 143495 issued by:

ÖTI - Institut für Ökologie, ID No. 0534

Technik und Innovation GmbH, Spengergasse 20, 1050 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

ÖTI - Institut für Ökologie, ID No. 0534

Technik und Innovation GmbH, Spengergasse 20, 1050 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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