

# 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,  
Singapore 609434, Singapore  
sempermed@semperitgroup.com

Authorized representative in the EU

**Semperit Technische Produkte GmbH**  
Modcenterstraße 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

## sempercare 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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