

EU 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: 9001570NOF-065RB-N-869

sempercure safe+

| Sizes | X-Small | Small | Medium | Large | X-Large |
|---------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Article codes | 826758031 3000003710 | 826758033 3000003711 | 826758035 3000003712 | 826758037 3000003713 | 826758039 3000003714 |

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. 2777/11641-04/E00-00 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, EN 421:2010



Andreas Wöss
Sr Vice President Sales



Released by: Christian Rohrbach

This signed document is valid for all translations attached.

Issued : Singapore, 2023-10-19

Expires: 2025-10-18

Version: 001

EU-KONFORMITÄTSERKLÄRUNG

MEDIZINPRODUKTEVERORDNUNG (EU) 2017/745
VERORDNUNG (EU) 2016/425 FÜR PERSÖNLICHE SCHUTZAUSRÜSTUNG

Hersteller

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

EU-Bevollmächtigter

Semperit Technische Produkte Gesellschaft m.b.H.
Triester Bundesstraße 26, 2632 Wimpassing, Austria
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SRN: AT-AR-000000735

Dieses Zertifikat ist gültig für die folgenden Produkte:

Nicht-steriler Untersuchungs- und Schutzhandschuh für den Einmalgebrauch

Klassifizierung: Klasse I gemäß Medizinprodukteverordnung (EU) 2017/745
Kategorie III gemäß PSA Verordnung (EU) 2016/425

Basic UDI-DI: 9001570NOF-065RB-N-869

sempercare safe+

| Größen | X-Small | Small | Medium | Large | X-Large |
|----------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Artikelnummern | 826758031 3000003710 | 826758033 3000003711 | 826758035 3000003712 | 826758037 3000003713 | 826758039 3000003714 |

Wir bestätigen hiermit unter alleiniger Verantwortung, dass die CE gekennzeichneten Produkte mit den Anforderungen der Medizinprodukteverordnung (EU) 2017/745 übereinstimmen.

Erklärung basierend auf Anhang IV. Klassifizierung gemäß Regel 5, Anhang VIII. Konformitätsbewertung gemäß Anhang II.

Angewandte Normen: 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

Wir bestätigen hiermit unter alleiniger Verantwortung, dass die oben genannten CE gekennzeichneten Produkte mit den maßgeblichen Bestimmungen der Verordnung (EU) 2016/425 für Persönliche Schutzausrüstung übereinstimmen und Gegenstand sind der EU-Baumusterprüfbescheinigung Nr. 2777/11641-04/E00-00 ausgestellt durch:

SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Die Produkte sind Gegenstand der Verfahren gemäß Annex VII (Module C2) der Verordnung (EU) 2016/425 unter Aufsicht von

SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Angewandte Normen: 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, EN 421:2010

Ausgestellt am: Singapore, 2023-10-19

Gültig bis: 2025-10-18

Version: 001

DÉCLARATION UE DE CONFORMITÉ

RÈGLEMENT POUR LES DISPOSITIFS MÉDICAUX (UE) 2017/745
RÈGLEMENT (UE) 2016/425 POUR L'ÉQUIPEMENT DE PROTECTION INDIVIDUELLE

Fabricant

Semperit Investments Asia Pte. Ltd.
8 Jurong Town Hall Road,
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SRN: SG-MF-000001645

Représentant UE

Semperit Technische Produkte Gesellschaft m.b.H.
Triester Bundesstraße 26, 2632 Wimpassing, Austria
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SRN: AT-AR-000000735

Ce certificat est valable pour les produits suivants :

Gant d'examen et de protection non-stérile à usage unique

Classification : Classe I selon la règlement pour dispositifs médicaux (UE) 2017/745
Catégorie III selon la règlement EPI (UE) 2016/425

Basic UDI-DI: 9001570NOF-065RB-N-869

sempercare safe+

| Tailles | X-Small | Small | Medium | Large | X-Large |
|-------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Numéros d'article | 826758031 3000003710 | 826758033 3000003711 | 826758035 3000003712 | 826758037 3000003713 | 826758039 3000003714 |

Par la présente, nous déclarons sous notre propre responsabilité que les produits portant le symbole CE sont conformes aux exigences de la règlement sur les dispositifs médicaux (EU) 2017/745.

La déclaration se fonde sur l'annexe IV. Classification selon la règle 5, annexe VIII. Évaluation de la conformité selon l'annexe II.

Normes appliquées : 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

Par la présente, nous déclarons sous notre propre responsabilité que les produits portant le symbole CE mentionnés ci-dessus sont conformes aux dispositions essentielles de la règlement (UE) 2016/425 concernant l'équipement de protection individuelle sont identiques à l'équipement de protection individuelle faisant l'objet du certificat d'examen de type UE numéro 2777/11641-04/E00-00 délivré par:

SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Les produits sont soumis aux procédures visées dans l'annexe VII (Module C2) de la règlement (UE) 2016/425 sous la surveillance de

SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Normes appliquées : 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, EN 421:2010

Délivré le : Singapore, 2023-10-19

Valable jusqu'au : 2025-10-18

Version: 001

DICHIARAZIONE DI CONFORMITÀ UE

REGOLAMENTO SUL DISPOSITIVO MEDICO (UE) 2017/745

REGOLAMENTO (UE) 2016/425 DELL'APPARECCHIATURA DI PROTEZIONE INDIVIDUALE

Produttore

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

Rappresentante autorizzato nell'UE

Semperit Technische Produkte Gesellschaft m.b.H.
Triester Bundesstraße 26, 2632 Wimpassing, Austria
sempermed@semperitgroup.com
SRN: AT-AR-000000735

Questo certificato è valido per il seguente prodotto:

Quanto protettivo non sterile monouso da esame

Classificazione: Classe I secondo il regolamento dispositivi medici (UE) 2017/745

Categoria III secondo il regolamento (UE) 2016/425 del PPE

Basic UDI-DI: 9001570NOF-065RB-N-869

sempercare safe+

| Misure | X-Small | Small | Medium | Large | X-Large |
|-----------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Codici articolo | 826758031 3000003710 | 826758033 3000003711 | 826758035 3000003712 | 826758037 3000003713 | 826758039 3000003714 |

Con la presente, dichiariamo sotto la nostra esclusiva responsabilità che il prodotto con marchio CE sopra descritto soddisfa i requisiti del regolamento sui dispositivi medici (UE) 2017/745 .

Dichiarazione basata sull'allegato IV. Classificazione secondo la regola 5, allegato VIII. La valutazione della conformità si basa sull'allegato II.

Norme applicate: 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

Con la presente, dichiariamo sotto la nostra esclusiva responsabilità che il prodotto con marchio CE sopra descritto è conforme alle disposizioni applicabili del Regolamento (UE) 2016/425 sui dispositivi di protezione individuale ed è identico al dispositivo di protezione personale che è soggetto al Certificato di Esame di Tipo UE n. 2777/11641-04/E00-00 rilasciato da:

SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

ed è soggetto alla procedura di cui all'allegato VII (modulo C2) del regolamento (UE) 2016/425 sotto il controllo di

SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Norme applicate: 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, EN 421:2010

Rilasciato : Singapore, 2023-10-19

Scade: 2025-10-18

Version: 001

EU-CONFORMITEITSVERKLARING

VERORDENING MEDISCHE PRODUCTEN (EU) 2017/745

VERORDENING (EU) 2016/425 BETREFFENDE PERSOONLIJKE BESCHERMENDE UITRUSTING

Fabrikant

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

Gemachtigde EU

Semperit Technische Produkte Gesellschaft m.b.H.
Triester Bundesstraße 26, 2632 Wimpassing, Austria
sempermed@semperitgroup.com
SRN: AT-AR-000000735

Dit certificaat is geldig voor de volgende producten:

Niet-steriele onderzoeks- en beschermende handschoenen voor eenmalig gebruik

Classificatie: Klasse I volgens Verordening (EU) 2017/745 betreffende medische hulpmiddelen
 Categorie III volgens PBM-verordening (EU) 2016/425

Basic UDI-DI: 9001570NOF-065RB-N-869

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| Artikelnummers | 826758031 3000003710 | 826758033 3000003711 | 826758035 3000003712 | 826758037 3000003713 | 826758039 3000003714 |

Wij verklaren hierbij onder uitsluitende verantwoordelijkheid, dat de CE-gemarkeerde producten voldoen aan de vereisten van de Verordening Medische Hulpmiddelen (EU) 2017/745.

Verklaring op basis van bijlage IV. Classificatie volgens regel 5, bijlage VIII. De conformiteitsbeoordeling is gebaseerd op bijlage II.

Toegepaste normen: 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

Hierbij verklaren wij onder uitsluitende verantwoordelijkheid, dat de bovengenoemde CE-gemarkeerde producten voldoen aan de relevante bepalingen van de Verordening (EU) 2016/425 over persoonlijke beschermingsmiddelen en het onderworpen zijn aan het certificaat van EU-typeonderzoek nr.2777/11641-04/E00-00 uitgegeven door:

SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

De producten vallen onder de procedures van bijlage VII (module C2) van de verordening (EU) 2016/425 onder toezicht van

SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Toegepaste normen: 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, EN 421:2010

Uitgegeven op:

Singapore, 2023-10-19

Geldig tot: 2025-10-18

Version: 001

DECLARACIÓN UE DE CONFORMIDAD

REGLAMENTO (UE) 2017/745 DE PRODUCTOS MEDICINALES
 REGLAMENTO (UE) 2016/425 PARA EQUIPAMIENTOS PERSONALES

Fabricante

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

Representante de la UE

Semperit Technische Produkte Gesellschaft m.b.H.
 Triester Bundesstraße 26, 2632 Wimpassing, Austria
 sempermed@semperitgroup.com
 SRN: AT-AR-000000735

El presente certificado es válido para los siguientes productos:

Guante de exploración y protección no estéril para un solo uso

Clasificación: Clase I según el Reglamento de Productos Medicinales (EU) 2017/745
 Categoría III según el Reglamento EPI (UE) 2016/425

Basic UDI-DI: 9001570NOF-065RB-N-869

sempercure safe+

| Tamaños | X-Small | Small | Medium | Large | X-Large |
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| Número de artículo | 826758031 3000003710 | 826758033 3000003711 | 826758035 3000003712 | 826758037 3000003713 | 826758039 3000003714 |

Por la presente confirmamos bajo nuestra exclusiva responsabilidad que los productos con marcado CE cumplen con los requisitos del Reglamento (UE) 2017/745 sobre productos sanitarios.

Declaración basada en el anexo IV. Clasificación según la norma 5 del anexo VIII. La evaluación de la conformidad se basa en el anexo II.

Normas aplicadas: 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

Por la presente confirmamos, bajo nuestra exclusiva responsabilidad, que los productos arriba mencionados con la marca CE cumplen con las disposiciones pertinentes del Reglamento (UE) 2016/425 para equipos de protección personal y están sujetos al Certificado de examen de tipo nº. 2777/11641-04/E00-00 expedido por:

SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Los productos están sujetos a los procedimientos establecidos en el anexo VII (módulo C2) del Reglamento (UE) 2016/425 bajo la supervisión de

SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Normas aplicadas: 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, EN 421:2010

Expedido el: Singapore, 2023-10-19

Válido hasta: 2025-10-18

Version: 001

DECLARAÇÃO DE CONFORMIDADE UE

REGULAMENTO (UE) 2017/745 SOBRE DISPOSITIVOS MÉDICOS
 REGULAMENTO (UE) 2016/425 SOBRE EQUIPAMENTO DE PROTEÇÃO INDIVIDUAL

Fabricante

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

Representante da UE

Semperit Technische Produkte Gesellschaft m.b.H.
 Triester Bundesstraße 26, 2632 Wimpassing, Austria
 sempermed@semperitgroup.com
 SRN: AT-AR-000000735

Este certificado é válido para os seguintes produtos:

Luva de exame e de proteção não estéril para uso único

Classificação: Classe I de acordo com o regulamento de Dispositivos Médicos (UE) 2017/745
 Categoria III de acordo com o regulamento EPI (UE) 2016/425

Basic UDI-DI: 9001570NOF-065RB-N-869

sempercare safe+

| Tamanhos | X-Small | Small | Medium | Large | X-Large |
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| Números de artigo | 826758031 3000003710 | 826758033 3000003711 | 826758035 3000003712 | 826758037 3000003713 | 826758039 3000003714 |

Declaramos desta forma, sob a nossa exclusiva responsabilidade, que os produtos com a marca CE estão em conformidade com os requisitos da Regulamento de Dispositivos Médicos (UE) 2017/745 .

Declaração baseada no Anexo IV. Classificação de acordo com a regra 5, Anexo VIII. Avaliação da conformidade com base no Anexo II.

Normas aplicadas: 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

Declaramos desta forma, sob a nossa exclusiva responsabilidade, que os produtos com a marca CE acima mencionados estão em conformidade com as disposições relevantes do regulamento (UE) 2016/425 para Equipamentos de Proteção Individual e são objeto do certificado de exame de tipo da UE n.º 2777/11641-04/E00-00 emitido por:

SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Os produtos são objeto dos procedimentos previstos no anexo VII (módulo C2) do regulamento (UE) 2016/425, sob a supervisão de

SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Normas aplicadas: 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, EN 421:2010

Emitido em: Singapore, 2023-10-19

Válido até: 2025-10-18

Version: 001

EU-FÖRSÄKRAN OM ÖVERENSSTÄMMELSE

FÖRORDNING (EU) 2017/745 MEDICINTEKNISKA PRODUKTER
FÖRORDNING (EU) 2016/425 FÖR PERSONLIG SKYDDSUTRUSTNING

Tillverkare

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

Behörig representant hos EU

Semperit Technische Produkte Gesellschaft m.b.H.
Triester Bundesstraße 26, 2632 Wimpassing, Austria
sempermed@semperitgroup.com
SRN: AT-AR-000000735

Detta certifikat gäller följande produkt:

Icke-steril inspektions- och skyddshandske för engångsanvändning

Klassificering: Klass I enligt EU-förordning för medicintekniska produkter (MD) (EU) 2017/745
Kategori III enligt EU-förordning för personlig skyddsutrustning (PPE) 2016/425

Basic UDI-DI: 9001570NOF-065RB-N-869

sempercure safe+

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| Artikelkoder | 826758031 3000003710 | 826758033 3000003711 | 826758035 3000003712 | 826758037 3000003713 | 826758039 3000003714 |

Vi förklarar härmed under eget exklusivt ansvar att ovan beskrivna, CE-markerade produkt stämmer överens med erforderliga i förordning för medicinska produkter (EU) 2017/745.

Förklaring på grundval av bilaga IV. Klassificering enligt regel 5, bilaga VIII. Bedömningen av överensstämmelse grundar sig på bilaga II.

Tillämpade standarder: 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

Vi förklarar härmed under eget exklusivt ansvar att ovan beskrivna, CE-markerade produkt stämmer överens med tillämpliga bestämmelser i EU-förordningen 2016/425 för personlig skyddsutrustning och är identisk med den personliga skyddsutrustning som anges i EU-certifikat för typgranskning nummer2777/11641-04/E00-00 daterad av:

SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

och är föremål för den procedur som beskrivs i Bilaga VII (Modul C2) till EU-förordningen 2016/425 under the supervision of under uppsikt av

SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Tillämpade standarder: 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, EN 421:2010

Daterad : Singapore, 2023-10-19

Giltig till: 2025-10-18

Version: 001

EU-OVERENSSTEMMELSESERKLÆRING

FORORDNING (EU) 2017/745 OM MEDICINSK Udstyr
FORORDNING (EU) 2016/425 FOR PERSONLIGE VÆRNEMIDLER

Producent

EU-befuldsmægtigede

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

Semperit Technische Produkte Gesellschaft m.b.H.
Triester Bundesstraße 26, 2632 Wimpassing, Austria
sempermed@semperitgroup.com
SRN: AT-AR-000000735

Dette certifikat er gyldigt for følgende produkter:

Ikke-steril undersøgelses- og beskyttelseshandske til engangsbrug

Klassificering: Klasse I jævnfør (EU) 2017/745 -forordningen for medicinsk udstyr
Kategori III jævnfør PVM-forordningen (EU) 2016/425

Basic UDI-DI: 9001570NOF-065RB-N-869

sempercure safe+

| Størrelser | X-Small | Small | Medium | Large | X-Large |
|--------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Artikelnumre | 826758031 3000003710 | 826758033 3000003711 | 826758035 3000003712 | 826758037 3000003713 | 826758039 3000003714 |

Vi bekræfter hermed under fuldt ansvar, at de ovenfor nævnte CE-mærkede produkter stemmer overens med de krav i forordningen for medicinsk udstyr (EU) 2017/745.

Erklæring på grundlag af bilag IV. Klassificering i henhold til regel 5, bilag VIII. Overensstemmelsesvurderingen er baseret på bilag II.

Anvendte standarder: 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

Vi bekræfter hermed under fuldt ansvar, at de ovenfor nævnte CE-mærkede produkter stemmer overens med de afgørende bestemmelser i forordningen (EU) 2016/425 for personlige værnemidler, og er genstand for EU-certificering af typeafprøvning nr.2777/11641-04/E00-00 udstedt gennem:

SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Produkterne er genstand for procedurer jævnfør VII (modul C2) i forordningen (EU) 2016/425 med opsyn af

SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Anvendte standarder: 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, EN 421:2010

Udstedt den: Singapore, 2023-10-19

Gyldig til: 2025-10-18

Version: 001

EU KONFORMITETSERKLÆRING

FORORDNING FOR MEDISINSK UTSTYR (EU) 2017/745
 FORORDNING (EU) 2016/425 OM PERSONLIG VERNEUTSTYR

Produsent

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

Autorisert representant i EU

Semperit Technische Produkte Gesellschaft m.b.H.
 Triester Bundesstraße 26, 2632 Wimpassing, Austria
 sempermed@semperitgroup.com
 SRN: AT-AR-000000735

Dette sertifikatet er gyldig for følgende produkter:

Ikke-steril undersøkelses- og beskyttelseshanske for engangsbruk

Klassifisering: Klasse I i henhold til forordning for medisinsk utstyr (EU) 2017/745
 Kategori III i henhold til PVU-forordningen (EU) nr. 2016/425

Basic UDI-DI: 9001570NOF-065RB-N-869

sempercare safe+

| Størrelser | X-Small | Small | Medium | Large | X-Large |
|---------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Artikkelnumre | 826758031 3000003710 | 826758033 3000003711 | 826758035 3000003712 | 826758037 3000003713 | 826758039 3000003714 |

Vi erklærer herved under eneansvar at det CE-merkede produktet oppfyller de kravene i Uredbet for medisinsk utstyr (EU) 2017/745.

Erklæring basert på vedlegg IV. Klassifisering i henhold til regel nr. 5, vedlegg VIII. Samsvarsvurderingen er basert på vedlegg II.

Relevante standarder: 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

Vi erklærer herved under eneansvar at det CE-merkede produktet som er nevnt ovenfor oppfyller de relevante bestemmelsene i Forordning (EU) nr. 2016/425 om personlig verneutstyr og er gjenstand for EU-typeprøvesertifikat nr. 2777/11641-04/E00-00 utstedt av:

SATRA Technology Europe Ltd, ID No. 2777
 Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Produktet er gjenstand for prosedyren som er beskrevet i Vedlegg VII (Modul C2) i Forordning nr. 2016/425 under tilsyn av **SATRA Technology Europe Ltd, ID No. 2777**
 Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Relevante standarder: 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, EN 421:2010

Utstedt den: Singapore, 2023-10-19

Gyldig til: 2025-10-18

Version: 001

EU-VAATIMUSTENMUKAISUUSVAKUUTUS

LÄÄKINNÄLLISIÄ LAITTEITA KOSKEVA ASETUS (EU) 2017/745

HENKILÖNSUOJAIMISTA ANNETTU ASETUS (EU) 2016/425

Valmistaja

EU:n valtuutettu edustaja

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

Semperit Technische Produkte Gesellschaft m.b.H.
Triester Bundesstraße 26, 2632 Wimpassing, Austria
sempermed@semperitgroup.com
SRN: AT-AR-000000735

Tämä sertifiikaatti koskee seuraavia tuotteita:

Kertakäyttöinen ei-steriili tutkimus- ja suojäkäsine

Luokitus: Luokka I lääkinnällisiä laitteita koskevan asetuksen (EU) 2017/745 mukaisesti
Luokka III henkilönsuojaimista annetun asetuksen (EU) 2016/425 mukaisesti

Basic UDI-DI: 9001570NOF-065RB-N-869

sempercure safe+

| Koot | X-Small | Small | Medium | Large | X-Large |
|--------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Tuotenumerot | 826758031 3000003710 | 826758033 3000003711 | 826758035 3000003712 | 826758037 3000003713 | 826758039 3000003714 |

Täten vahvistamme yksinomaisella vastuullamme, että CE-merkityt tuotteet vastaavat lääkinnällisiä laitteita koskevan asetuksen (EU) 2017/745 mukaisia vaatimuksia.

Liitteeseen IV perustuva julistus. Luokitus liitteen VIII 5 säännön mukaisesti. Vaatimustenmukaisuuden arviointi perustuu liitteeseen II.

Sovellatut standardit: 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

Täten vahvistamme yksinomaisella vastuullamme, että yllä mainitut CE-merkityt tuotteet vastaavat henkilönsuojaimista annetun asetuksen (EU) 2016/425 mukaisia perustavanlaatuisia vaatimuksia ja niihin sovelletaan EU:n tyyppitarkastustodistusta nro 2777/11641-04/E00-00 laadittu :

SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Tuotteet ovat asetuksen (EU) 2016/425 liitteen VII (moduuli C2) mukaisen menettelyn kohteena, valvonnan suorittaa

SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Sovellatut standardit: 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, EN 421:2010

Laadittu : Singapore, 2023-10-19 Voimassa (asti): 2025-10-18 Version: 001

ES ATITIKTIES DEKLARACIJA

REGLAMENTAS DĖL MEDICINOS PRIETAISŲ (ES) 2017/745
 REGLAMENTAS (ES) 2016/425 DĖL ASMENINIŲ APSAUGOS PRIEMONIŲ

Gamintojas

ES įgaliotas asmuo

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

Semperit Technische Produkte Gesellschaft m.b.H.
 Triester Bundesstraße 26, 2632 Wimpassing, Austria
 sempermed@semperitgroup.com
 SRN: AT-AR-000000735

Šis sertifikatas galioja toliau nurodytiems produktams:

Nesterilios vienkartinio naudojimo apžiūros ir apsauginės pirštinės

Klasifikacija: I klasė pagal reglamentą dėl medicinos prietaisų (ES) 2017/745
 III kategorija pagal reglamentą (ES) 2016/425 dėl asmeninių apsaugos priemonių

Basic UDI-DI: 9001570NOF-065RB-N-869

sempercare safe+

| Dydžiai | X-Small | Small | Medium | Large | X-Large |
|-----------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Prekių numeriai | 826758031 3000003710 | 826758033 3000003711 | 826758035 3000003712 | 826758037 3000003713 | 826758039 3000003714 |

Prisiimdami visą atsakomybę šiuo dokumentu patvirtiname, kad CE paženklininti produktai atitinka reglamentą dėl medicinos prietaisų (ES) 2017/745 reikalavimus.

Deklaracija, pagrįsta IV priedu. Klasifikavimas pagal VIII priedo 5 taisyklę. Atitikties įvertinimas pagal II priedą.

Taikomi standartai: 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

Prisiimdami visą atsakomybę, šiuo dokumentu patvirtiname, kad anksčiau paminėti CE paženklininti produktai atitinka svarbiausius reglamentą dėl asmeninių apsaugos priemonių (ES) 2016/425 reikalavimus ir yra ES tipo tyrimo sertifikato Nr. objektas. 2777/11641-04/E00-00 išduota :

SATRA Technology Europe Ltd, ID No. 2777
 Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Produktai yra metodo objektas pagal reglamentą (ES) 2016/425 VII priedą (modulis C2) prižiūrint

SATRA Technology Europe Ltd, ID No. 2777
 Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Taikomi standartai: 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, EN 421:2010

Išduota : Singapore,

2023-10-19

Galioja iki: 2025-10-18

Version: 001

ES ATBILSTĪBAS DEKLARĀCIJA

MEDICĪNAS IERĪČU REGULĀ (ES) 2017/745

REGULA (ES) 2016/425 PAR INDIVIDUĀLAJĒM AIZSARDZĪBAS LĪDZEKĻIEM

Likumīgais ražotājs

Pilnvarotais pārstāvis ES

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

Semperit Technische Produkte Gesellschaft m.b.H.
Triester Bundesstraße 26, 2632 Wimpassing, Austria
sempermed@semperitgroup.com
SRN: AT-AR-000000735

Šis sertifikāts ir derīgs šādam produktam:

Nesterili izmeklēšanas aizsargcimdi vienreizējai lietošanai

Klasifikācija: I klase saskaņā ar medicīnas ierīču Regulu (ES) 2017/745
 III kategorija saskaņā ar IAL Regulu (ES) 2016/425

Basic UDI-DI: 9001570NOF-065RB-N-869

sempercare safe+

| Izmēri | X-Small | Small | Medium | Large | X-Large |
|-----------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Artikula numurs | 826758031 3000003710 | 826758033 3000003711 | 826758035 3000003712 | 826758037 3000003713 | 826758039 3000003714 |

Ar šo mēs apliecinām, ka iepriekš aprakstītais produkts ar CE marķējumu atbilst medicīnas ierīču (ES) 2017/745 regulas prasībām.

Deklarācija, pamatojoties uz IV pielikumu. Klasifikācija saskaņā ar VIII pielikuma 5. noteikumu. Atbilstības novērtēšanas pamatā ir II pielikums.

Piemērotie standarti: 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

Ar šo mēs apliecinām, ka iepriekš aprakstītais produkts ar CE marķējumu atbilst Regulas (ES) 2016/425 par individuālajiem aizsardzības līdzekļiem piemērojamajiem noteikumiem un ir identisks individuālajiem aizsardzības līdzekļiem, uz kuriem attiecas ES tipa pārbaudes sertifikāts Nr. 2777/11641-04/E00-00 izdots :

SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

un uz to attiecas Regulas (ES) 2016/425 VII pielikumā (C2 modulis) noteiktā procedūra

SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Piemērotie standarti: 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, EN 421:2010

Izdots : Singapore, 2023-10-19

Derīgs līdz: 2025-10-18

Version: 001

ELI VASTAVUSDEKLARATSIOON

MEDITSIINITOODETE MÄÄRUS (EL) 2017/745
ISIKUKAITSEVAHENDITE MÄÄRUS (EL) 2016/425

Tootja

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

Volitatud esindaja EL-is

Semperit Technische Produkte Gesellschaft m.b.H.
Triester Bundesstraße 26, 2632 Wimpassing, Austria
sempermed@semperitgroup.com
SRN: AT-AR-000000735

See sertifikaat kehtib järgmistele toodetele:

Mittesteriiline läbivaatus- ja kaitsekinnas ühekordseks kasutuseks

Klassifikatsioon: I klass kooskõlas meditsiinitoodete määrusega (EU) 2017/745
III kategooria kooskõlas isikukaitsevahendite määrusega (EL) 2016/425

Basic UDI-DI: 9001570NOF-065RB-N-869

sempercare safe+

| Suurused | X-Small | Small | Medium | Large | X-Large |
|--------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Tootenumbrid | 826758031 3000003710 | 826758033 3000003711 | 826758035 3000003712 | 826758037 3000003713 | 826758039 3000003714 |

Kinnitame oma ainuvastutusel, et CE-märgisega tooted on kooskõlas meditsiinitoodete määruse (EU) 2017/745 nõuetega.

Deklaratsioon põhineb IV lisal. Klassifikatsioon kooskõlas VIII lisa 5. reegluga. Vastavushindamine põhineb II lisal.

Kohaldatud normid: 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

Kinnitame oma ainuvastutusel, et eespool nimetatud CE-märgistusega tooted on kooskõlas isikukaitsevahendite määruse (EL) 2016/425 põhisätetega ning on identsed isikukaitsevahenditega, mille kohta on välja antud EÜ tüübihindamistöend nr2777/11641-04/E00-00 välja :

SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Toodetele kohaldub määruse (EL) 2016/425 VII lisa (moodul C2) menetlus, mille üle teostab järelevalvet

SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Kohaldatud normid: 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, EN 421:2010

Välja andmise aeg :

Singapore, 2023-10-19

Kehtivusaeg: 2025-10-18

Version: 001

EU PROHLÁŠENÍ O SHODĚ

NAŘÍZENÍ O ZDRAVOTNICKÝCH PROSTŘEDCÍCH (EU) 2017/745
 NAŘÍZENÍ (EU) 2016/425 PRO OSOBNÍ OCHRANNÉ PROSTŘEDKY

Výrobce

EU zplnomocněný zástupce

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

Semperit Technische Produkte Gesellschaft m.b.H.
 Triester Bundesstraße 26, 2632 Wimpassing, Austria
 sempermed@semperitgroup.com
 SRN: AT-AR-000000735

Tento certifikát je platný pro následující produkty:

Nesterilní vyšetřovací a ochranné rukavice pro jednorázové použití

Klasifikace Třída I podle nařízení o zdravotnických prostředcích (EU) 2017/745
 Kategorie III podle nařízení o OOP (EU) 2016/425

Basic UDI-DI: 9001570NOF-065RB-N-869

sempercare safe+

| Velikosti | X-Small | Small | Medium | Large | X-Large |
|----------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Číslo produktu | 826758031 3000003710 | 826758033 3000003711 | 826758035 3000003712 | 826758037 3000003713 | 826758039 3000003714 |

Tímto potvrzujeme s výlučnou odpovědností, že produkty označené CE souhlasí se požadavky nařízení o zdravotnických prostředcích (EU) 2017/745.

Prohlášení na základě přílohy IV. Klasifikace podle pravidla 5 přílohy VIII. Posouzení shody je založeno na příloze II.

Použité normy: 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

Tímto potvrzujeme s výlučnou odpovědností, že výše uvedené produkty označené jako CE souhlasí s příslušnými ustanoveními nařízení (EU) 2016/425 pro Osobní ochranné prostředky a jsou předmětem přezkoušení EU č.2777/11641-04/E00-00 vystaveno :

SATRA Technology Europe Ltd, ID No. 2777
 Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Produkty jsou předmětem procesu podle dodatku VII (moduly, C2) nařízení (EU) 2016/425 pod dohledem

SATRA Technology Europe Ltd, ID No. 2777
 Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Použité normy: 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, EN 421:2010

Vystaveno dne:

Singapore, 2023-10-19

Platné do: 2025-10-18

Version: 001

EÚ VYHLÁSENIE O ZHODE

NARIADENIE (EU) 2017/745 O ZDRAVOTNÍCKYCH POMÔCKACH
NARIADENIE (EÚ) 2016/425 O OSOBNÝCH OCHRANNÝCH PROSTRIEDKOCH

Výrobca

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

Splnomocnenec pre EÚ

Semperit Technische Produkte Gesellschaft m.b.H.
Triester Bundesstraße 26, 2632 Wimpassing, Austria
sempermed@semperitgroup.com
SRN: AT-AR-000000735

Tento certifikát je platný pre nasledujúce body:

Nesterilné vyšetrovacie a ochranné rukavice na jedno použitie

Klasifikácia: Trieda I podľa Nariadenia (EU) 2017/745 o zdravotníckych pomôckach
Kategória III podľa Nariadenia o osobných ochranných pomôckach (EU) 2016/425

Basic UDI-DI: 9001570NOF-065RB-N-869

sempercare safe+

| Veľkosť | X-Small | Small | Medium | Large | X-Large |
|---------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Výrobné čísla | 826758031 3000003710 | 826758033 3000003711 | 826758035 3000003712 | 826758037 3000003713 | 826758039 3000003714 |

Týmto vo svojej výhradnej zodpovednosti potvrdzujeme, že výrobky označené symbolom CE sú v súlade so požiadavkami Nariadenia (EU) 2017/745 o zdravotníckych pomôckach.

Vyhlásenie na základe prílohy IV. Klasifikácia podľa pravidla 5 prílohy VIII. Posudzovanie zhody je založené na prílohe II.

Súvisiace normy: 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

Týmto vo svojej výhradnej zodpovednosti potvrdzujeme, že výrobky označené symbolom CE sú v súlade so smerodajnými ustanoveniami Nariadenia (EÚ) 2016/425 o osobných ochranných prostriedkoch a sú predmetom EU - Osvedčenia o typej skúške č. 2777/11641-04/E00-00 vyhotovené :

SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Výrobky sú predmetom konania podľa dodatku VII (moduly C2) Nariadenia (EÚ) 2016/425 pod dohľadom
SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Súvisiace normy: 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, EN 421:2010

Vyhotovené dňa:

Singapore, 2023-10-19

Platné do: 2025-10-18

Version: 001

EU-MEGFELELŐSÉGI NYILATKOZAT

ORVOSTECHNIKAI ESZKÖZÖKRŐL SZÓLÓ (EU) 2017/745 RENDELET
EGYÉNI VÉDŐESZKÖZÖKRŐL SZÓLÓ (EU) 2016/425 RENDELET

Gyártó

EU-meghatalmazott

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

Semperit Technische Produkte Gesellschaft m.b.H.
Triester Bundesstraße 26, 2632 Wimpassing, Austria
sempermed@semperitgroup.com
SRN: AT-AR-000000735

Ez a tanúsítvány a következő termékekre érvényes:

Egyszer használatos, nem steril vizsgáló- és védőkesztyű

Osztályozás: I. osztály az orvostechnikai eszközökről szóló (EU) 2017/745 rendelet szerint
III. kategória az egyéni védőeszközökről szóló (EU) 2016/425 rendelet szerint

Basic UDI-DI: 9001570NOF-065RB-N-869

sempercare safe+

| Méret | X-Small | Small | Medium | Large | X-Large |
|------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Cikkszámok | 826758031 3000003710 | 826758033 3000003711 | 826758035 3000003712 | 826758037 3000003713 | 826758039 3000003714 |

Ezennel kizárólagos felelősségünk mellett kijelentjük, hogy a fent említett CE jelzésű termékek megfelelnek az orvostechnikai eszközökről szóló (EU) 2017/745 rendelet alapvető előírásainak.

Nyilatkozat a IV. mellékleten alapszik. Osztályozás a VIII. melléklet, 5. szabálya szerint. Megfelelősségi értékelés a II. mellékleten alapul.

Alkalmazott szabványok: 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

Ezennel kizárólagos felelősségünk mellett kijelentjük, hogy a fent említett CE jelzésű termékek megfelelnek az egyéni védőeszközökre irányuló 2016/425/EU rendelet vonatkozó előírásainak és vonatkozik rájuk a megfelelő számú EU-típusvizsgálati tanúsítvány 2777/11641-04/E00-00 kelt :

**SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland**

A termékekre az (EU) 2016/425 rendelet VII. melléklete (C2 modul) szerinti eljárás vonatkozik a következők felügyelete alatt:

**SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland**

Alkalmazott szabványok: 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, EN 421:2010

Kelt : Singapore, 2023-10-19

Érvényes: 2025-10-18

Version: 001

IZJAVA EU 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
SRN: SG-MF-000001645

Pooblaščen zastopnik EU

Semperit Technische Produkte Gesellschaft m.b.H.
Triester Bundesstraße 26, 2632 Wimpassing, Austria
sempermed@semperitgroup.com
SRN: AT-AR-000000735

To potrnilo 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: 9001570NOF-065RB-N-869

sempercare safe+

| Velikosti | X-Small | Small | Medium | Large | X-Large |
|-------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Številke izdelkov | 826758031 3000003710 | 826758033 3000003711 | 826758035 3000003712 | 826758037 3000003713 | 826758039 3000003714 |

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. 2777/11641-04/E00-00 izdano :

SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Izdelki so predmet postopka v skladu s Prilogo VII (modul C2) uredbe (EU) 2016/425 pod nadzorom

SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Uporabljeni standardi: 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, EN 421:2010

Izdano dne:

Singapore, 2023-10-19

Veljavno do: 2025-10-18

Version: 001

EU IZJAVA O SUKLADNOSTI

UREDBA O MEDICINSKIM PROIZVODIMA (EU) 2017/745
UREDBA (EU) 2016/425 O OSOBNOJ ZAŠTITNOJ OPREMI

Proizvođač

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

Ovlašteni predstavnik u EU

Semperit Technische Produkte Gesellschaft m.b.H.
Triester Bundesstraße 26, 2632 Wimpassing, Austria
sempermed@semperitgroup.com
SRN: AT-AR-000000735

Ovaj certifikat vrijedi za sljedeće proizvode:

Nesterilne zaštitne rukavice za pregled za jednokratnu uporabu

Klasifikacija: Klasa I. prema Direktivi o medicinskim proizvodima (EU) 2017/745
Kategorija III. prema Uredbi o osobnoj zaštitnoj opremi (EU) 2016/425
Basic UDI-DI: 9001570NOF-065RB-N-869

sempercare safe+

| Veličine | X-Small | Small | Medium | Large | X-Large |
|-------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Br. artikla | 826758031 3000003710 | 826758033 3000003711 | 826758035 3000003712 | 826758037 3000003713 | 826758039 3000003714 |

Ovim putem izjavljujemo pod punom odgovornošću da su proizvodi s CE oznakom sukladni s zahtjevima Uredbe o medicinskim proizvodima (EU) 2017/745.

Izjava se temelji na Prilogu IV. Klasifikacija prema pravilu 5, Prilog VIII. Ocjenjivanje sukladnosti prema Prilogu II.

Primijenjene norme: 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

Ovim putem izjavljujemo pod punom odgovornošću da su prethodno navedeni proizvodi s CE oznakom sukladni s mjerodavnim odredbama Uredbe (EU) 2016/425 o osobnoj zaštitnoj opremi i da su predmet EU certifikata o ispitivanju tipa br.2777/11641-04/E00-00 izdano :

SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Proizvodi podliježu postupku iz Dodatka VII. (modul C2) Uredbe (EU) 2016/425 pod nadzorom

SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Primijenjene norme: 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, EN 421:2010

Izdano dana: Singapore, 2023-10-19

Vrijedi do: 2025-10-18

Version: 001

DEKLARACJA ZGODNOŚCI UE

ROZPORZĄDZENIE W SPRAWIE WYROBÓW MEDYCZNYCH (UE) 2017/745
ROZPORZĄDZENIE W SPRAWIE ŚRODKÓW OCHRONY INDYWIDUALNEJ (UE) 2016/425

Producent

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

Autoryzowany przedstawiciel w UE

Semperit Technische Produkte Gesellschaft m.b.H.
Triester Bundesstraße 26, 2632 Wimpassing, Austria
sempermed@semperitgroup.com
SRN: AT-AR-000000735

Niniejszy certyfikat obowiązuje w odniesieniu do następującego produktu:

Niesterylne rękawice medyczne i ochronne jednorazowego użytku

Klasyfikacja: Klasa I zgodnie z rozporządzeniem (UE) 2017/745 w sprawie wyrobów medycznych
Kategoria III zgodnie z rozporządzeniem (UE) 2016/425 w sprawie środków ochrony indywidualnej

Basic UDI-DI: 9001570NOF-065RB-N-869

sempercare safe+

| Rozmiary | X-Small | Small | Medium | Large | X-Large |
|------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Numery artykułów | 826758031 3000003710 | 826758033 3000003711 | 826758035 3000003712 | 826758037 3000003713 | 826758039 3000003714 |

Niniejszym oświadczamy, na naszą wyłączną odpowiedzialność, że opisany powyżej produkt z oznakowaniem CE jest zgodny z wymogami rozporządzenia w sprawie wyrobów medycznych (UE) 2017/745.

Deklaracja na podstawie załącznika IV. Klasyfikacja jest zgodna z zasadą 5, załącznik VIII. Ocenę zgodności przeprowadza się na podstawie załącznika II.

Zastosowane normy: 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

Na własną odpowiedzialność oświadczamy niniejszym, że opisany powyżej produkt z oznakowaniem CE jest zgodny z obowiązującymi przepisami rozporządzenia (UE) 2016/425 w sprawie środków ochrony indywidualnej i jest identyczny ze środkami ochrony indywidualnej, których dotyczy certyfikat badania typu UE nr 2777/11641-04/E00-00 data przez:

SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Produkty podlegają procedurze określonej w załączniku VII (moduł C2) rozporządzenia (UE) 2016/425 pod nadzorem

SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Zastosowane normy: 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, EN 421:2010

Data wydania: Singapore, 2023-10-19 Data ważności: 2025-10-18 Version: 001

DECLARAȚIA DE CONFORMITATE UEREGULAMENTULUI PRIVIND PRODUSELE MEDICALE (EU) 2017/745
REGULAMENTULUI (EU) 2016/425 PENTRU ECHIPAMENTUL PERSONAL DE PROTECȚIE

Producător

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

Persoană împuternicită EU

Semperit Technische Produkte Gesellschaft m.b.H.
Triester Bundesstraße 26, 2632 Wimpassing, Austria
sempermed@semperitgroup.com
SRN: AT-AR-000000735

Acest certificat este valabil pentru următoarele produse:

Mănușă de consult și de protecție nesterilă de unică folosințăclasificare: Clasa I conform reglementii privind produsele medicale (EU) 2017/745
Categorii III conform ordonanței EPP (EU) 2016/425

Basic UDI-DI: 9001570NOF-065RB-N-869

sempercare safe+

| mărimi | X-Small | Small | Medium | Large | X-Large |
|----------------------|------------|------------|------------|------------|------------|
| Numerele de articole | 826758031 | 826758033 | 826758035 | 826758037 | 826758039 |
| | 3000003710 | 3000003711 | 3000003712 | 3000003713 | 3000003714 |

Prin prezenta confirmăm preluând toată responsabilitatea că produsele marcate CE corespund cerințelor din Regulamentului privind produsele medicale (EU) 2017/745 .

Declarație bazată pe anexa IV. Clasificare în conformitate cu regula 5, anexa VIII. Evaluarea conformității se bazează pe anexa II.

Normele aplicate: 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

Prin prezenta confirmăm preluând toată responsabilitatea că produsele marcate CE indicate mai sus corespund cerințelor de bază (EU) 2016/425 pentru echipamente personale de protecție și acestea sunt obiectul certificării de tip CE nr. 2777/11641-04/E00-00 eliberat prin:**SATRA Technology Europe Ltd, ID No. 2777**
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Produsele fac obiectul procedurii prevăzute în anexa VII (modulul C2) la Regulamentul (UE) 2016/425, sub supravegherea

SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Normele aplicate: 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, EN 421:2010

Eliberat la data de:

Singapore, 2023-10-19

Valabil până în:

2025-10-18

Version: 001

ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ ΕΕ

ΚΑΝΟΝΙΣΜΟΣ (ΕΕ) 2017/745 ΠΕΡΙ ΙΑΤΡΟΤΕΧΝΟΛΟΓΙΚΩΝ ΠΡΟΪΟΝΤΩΝ
ΚΑΝΟΝΙΣΜΟΣ (ΕΕ) 2016/425 ΠΕΡΙ ΜΕΣΩΝ ΑΤΟΜΙΚΗΣ ΠΡΟΣΤΑΣΙΑΣ

Κατασκευαστής

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

Εξουσιοδοτημένος αντιπρόσωπος στην ΕΕ

Semperit Technische Produkte Gesellschaft m.b.H.
Triester Bundesstraße 26, 2632 Wimpassing, Austria
sempermed@semperitgroup.com
SRN: AT-AR-000000735

Το παρόν πιστοποιητικό ισχύει για τα ακόλουθα προϊόντα:

Μη αποστειρωμένο γάντι εξέτασης και προστατευτικό γάντι μιας χρήσης

Ταξινόμηση: Κατηγορία I σύμφωνα με την Κανονισμό (ΕΥ) 2017/745 περί ιατροτεχνολογικών προϊόντων
Κατηγορία II σύμφωνα με τον Κανονισμό (ΕΕ) 2016/425 περί ΜΑΠ

Basic UDI-DI: 9001570NOF-065RB-N-869

sempercure safe+

| Μεγέθη | X-Small | Small | Medium | Large | X-Large |
|-------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Αριθμοί προϊόντος | 826758031 3000003710 | 826758033 3000003711 | 826758035 3000003712 | 826758037 3000003713 | 826758039 3000003714 |

Δια του παρόντος βεβαιώνουμε υπεύθυνα ότι τα προϊόντα με σήμανση CE ικανοποιούν τις απαιτήσεις της Κανονισμός (ΕΥ) 2017/745 περί ιατροτεχνολογικών προϊόντων.

Δήλωση με βάση το παράρτημα IV. Ταξινόμηση σύμφωνα με τον κανόνα 5, παράρτημα VIII. Η αξιολόγηση της συμμόρφωσης βασίζεται στο παράρτημα II.

Εφαρμοζόμενα πρότυπα: 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

Δια του παρόντος βεβαιώνουμε υπεύθυνα ότι τα ανωτέρω προϊόντα με σήμανση CE ικανοποιούν τις εφαρμοστέες διατάξεις του Κανονισμού (ΕΕ) 2016/425 περί μέσων ατομικής προστασίας και αποτελούν αντικείμενο του πιστοποιητικού εξέτασης τύπου ΕΕ με αρ. 2777/11641-04/E00-00 εκδόθηκε :

SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Τα προϊόντα αποτελούν αντικείμενο της μεθόδου που ορίζεται στο Παράρτημα VII (ενότητα C2) του Κανονισμού (ΕΕ) 2016/425 υπό την επιτήρηση

SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Εφαρμοζόμενα πρότυπα: 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, EN 421:2010

ЕС ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕРЕГЛАМЕНТ ЗА МЕДИЦИНСКИТЕ ПРОДУКТИ (EU) 2017/745
РЕГЛАМЕНТ (EU) 2016/425 ЗА ЛИЧНИТЕ ПРЕДПАЗНИ СРЕДСТВА

Производител

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

Упълномощен представител в ЕС

Semperit Technische Produkte Gesellschaft m.b.H.
Triester Bundesstraße 26, 2632 Wimpassing, Austria
sempermed@semperitgroup.com
SRN: AT-AR-000000735

Настоящият сертификат важи за следните продукти:

Нестерилна ръкавица за преглед и предпазна ръкавица за еднократна употребаКласификация: Клас I съгл. Регламент за медицинските продукти (EU) 2017/745
Категория III съгл. Регламент за ЛПС (EU) 2016/425

Basic UDI-DI: 9001570NOF-065RB-N-869

sempercare safe+

| Размери | X-Small | Small | Medium | Large | X-Large |
|----------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Номера на артикулите | 826758031 3000003710 | 826758033 3000003711 | 826758035 3000003712 | 826758037 3000003713 | 826758039 3000003714 |

С настоящето потвърждаваме при самостоятелна отговорност, че продуктите с маркировка CE съответстват на изисквания от Регламент за медицинските продукти (EU) 2017/745.

Декларация въз основа на приложение IV. Класификация съгласно правило 5, приложение VIII. Оценката на съответствието се основава на приложение II.

Приложими норми: 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

С настоящето потвърждаваме при самостоятелна отговорност, че горепосочените продукти с маркировка CE съответстват на съществените разпоредби на Регламент (EU) 2016/425 за личните предпазни средства и са предмет на сертификата на ЕС за изследване на типа Nr. 2777/11641-04/E00-00 издадено чрез:**SATRA Technology Europe Ltd, ID No. 2777**
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Продуктите са предмет на процедурата съгл. Анекс VII (Модул C2) от Регламента (EU) 2016/425 под надзора на

SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Приложими норми: 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, EN 421:2010

Издадено на: Singapore, 2023-10-19

Важи до: 2025-10-18

Version: 001

UYGUNLUK BEYANI

TIBBİ CİHAZLAR HAKKINDA 2017/745 TÜZÜĞÜ (AB)
KİŞİSEL KORUYUCU EKİPMANLAR İÇİN (AB) 2016/425 NOLU TÜZÜK

Üretici

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Bu sertifika aşağıdaki ürün için geçerlidir:

Tek kullanımlık steril olmayan muayene ve koruyucu eldiven

Sınıflandırma: Tıbbi cihazlarla ilgili 2017/745 (AB) sayılı Tüzük uyarınca Sınıf I
KKE Yönetmeliği (AB) 2016/425 uyarınca Kategori III

Basic UDI-DI: 9001570NOF-065RB-N-869

sempercare safe+

| Boyutlar | X-Small | Small | Medium | Large | X-Large |
|-----------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Ürün numaraları | 826758031 3000003710 | 826758033 3000003711 | 826758035 3000003712 | 826758037 3000003713 | 826758039 3000003714 |

Yukarıda açıklanan CE işaretli ürünün (AB) 2017/745 sayılı tıbbi cihazlara ilişkin Yönetmeliği koşullarına uygun olduğunu tek sorumluluğumuzda beyan ederiz.

Ek IV'e dayalı beyan. Kural 5, Ek VIII'e göre sınıflandırma. Uygunluk değerlendirmesi Ek II'a dayanmaktadır.

Uygulamalı standartlar: 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

Yukarıda açıklanan CE işaretli ürünün, (AB) 2016/425 sayılı Kişisel Koruyucu Ekipman Tüzüğü'nün belirleyici hükümlerine uygun olduğunu ve AB Tipi Muayene Sertifika Numarasına tabi olduğunu beyan ederiz. 2777/11641-04/E00-00 verilmiş :

SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Ürünler, aşağıdakilerin gözetimi altında 2016/425 sayılı Tüzüğü'nün (AB) Ek VII'sinde (Modül C2) belirtilen prosedüre tabidir
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Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Uygulamalı standartlar: 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, EN 421:2010

Veriliş tarihi: Singapore, 2023-10-19

Son geçerlilik tarihi: 2025-10-18

Version: 001