sempermed®

DECLARATION OF CONFORMITY

MEDICAL DEVICE DIRECTIVE 93/42/EEC

Legal Manufacturer

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

Authorized representative in the EU

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

This certificate is valid for the following product:

Sterile surgical glove for single use
Classification: Class IIa according to MD Directive 93/42/EEC

sempermed supreme (USA)

Sizes	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Article codes	822751527	822751607	822751627	822751707	822751727	822751807	822751827	822751907
	3000006119	3000006120	3000006121	3000006122	3000006123	3000006124	3000006125	3000006126

We hereby declare under sole responsibility that the CE 0123 marked product described above conforms to the essential requirements (Annex I) of the directive for medical devices 93/42/EEC.

Declaration based on Annex II excluding (4). Classification according rule 6, appendix IX.

Applied standards: ASTM D3577-19, 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 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, 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

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EC Certificate No.: G1 088308 0018 Rev. 00

Andreas Wöss
Sr Vice President Sales

Released by: Christian Rohrbach

Issued : Singapore, 2024-01-10 **Expires:** 2026-01-09

This signed document is valid for all translations attached.

KONFORMITÄTSERKLÄRUNG

MEDIZINPRODUKTERICHTLINIE 93/42/EWG

Hersteller

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

EU-Bevollmächtigter

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

Dieses Zertifikat ist gültig für die folgenden Produkte:

Steriler Operationshandschuh für den Einmalgebrauch
Klassifizierung: Klasse IIa gemäß Medizinprodukterichtlinie 93/42/EWG

sempermed supreme (USA)

Größen	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Artikelnummern	822751527	822751607	822751627	822751707	822751727	822751807	822751827	822751907
	3000006119	3000006120	3000006121	3000006122	3000006123	3000006124	3000006125	3000006126

Wir bestätigen hiermit unter alleiniger Verantwortung, dass die CE 0123 gekennzeichneten Produkte mit den grundlegenden Anforderungen (Anhang I) der Medizinprodukterichtlinie 93/42/EWG übereinstimmen.

Erklärung basierend auf Anhang II exklusive (4). Klassifizierung gemäß Regel 6, Anhang IX.

Angewandte Normen: ASTM D3577-19, 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 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, 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

Benannte Stelle: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EC Certificate No.: G1 088308 0018 Rev. 00

Ausgestellt am: Singapore, 2024-01-10 **Gültig bis:** 2026-01-09

DÉCLARATION DE CONFORMITÉ

DIRECTIVE SUR LES DISPOSITIFS MÉDICAUX 93/42/CEE

Fabricant

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

Représentant UE

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

Ce certificat est valable pour les produits suivants :

Gant chirurgical stérile à usage unique
Classification : Classe IIa selon la directive pour dispositifs médicaux 93/42/EEC

sempermed supreme (USA)

Tailles	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Numéros d'article	822751527	822751607	822751627	822751707	822751727	822751807	822751827	822751907
	3000006119	3000006120	3000006121	3000006122	3000006123	3000006124	3000006125	3000006126

Par la présente, nous déclarons sous notre propre responsabilité que les produits portant le symbole CE 0123 sont conformes aux exigences essentielles (Annexe I) de la directive sur les dispositifs médicaux 93/42/CEE.

La déclaration se fonde sur l'annexe II mis à part (4). Classification selon la règle 6, annexe IX.

Normes appliquées : ASTM D3577-19, 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 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, 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

Organisme notifié : TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EC Certificate No.: G1 088308 0018 Rev. 00

Délivré le : Singapore, 2024-01-10 **Valable jusqu'au :** 2026-01-09

DICHIARAZIONE DI CONFORMITÀ

DIRETTIVA SUL DISPOSITIVO MEDICO 93/42 / CEE

Produttore

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

Rappresentante autorizzato nell'UE

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

Questo certificato è valido per il seguente prodotto:

Guanto chirurgico sterile monouso
Clasificazione: Classe IIa secondo la direttiva MD 93/42 / CEE

sempermed supreme (USA)

Misure	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Codici articolo	822751527	822751607	822751627	822751707	822751727	822751807	822751827	822751907
	3000006119	3000006120	3000006121	3000006122	3000006123	3000006124	3000006125	3000006126

Con la presente, dichiariamo sotto la nostra esclusiva responsabilità che il prodotto con marchio CE 0123 sopra descritto soddisfa i requisiti essenziali (allegato I) della direttiva sui dispositivi medici 93/42 / CEE.

Dichiarazione basata sull'allegato II escluso (4). Classificazione secondo la regola 6, appendice IX.

Norme applicate: ASTM D3577-19, 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 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, 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

Organismo notificato: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EC Certificate No.: G1 088308 0018 Rev. 00

Rilasciato : Singapore, 2024-01-10 **Scade:** 2026-01-09

CONFORMITEITSVERKLARING

RICHTLIJN MEDISCHE PRODUCTEN 93/42 / EEG

Fabrikant

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

Gemachtigde EU

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

Dit certificaat is geldig voor de volgende producten:

Steriele chirurgische handschoen voor eenmalig gebruik
Classificatie: Klasse IIa volgens Richtlijn 93/42 / EEG betreffende medische hulpmiddelen

sempermed supreme (USA)

Maten	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Artikelnummers	822751527	822751607	822751627	822751707	822751727	822751807	822751827	822751907
	3000006119	3000006120	3000006121	3000006122	3000006123	3000006124	3000006125	3000006126

Wij verklaren hierbij onder uitsluitende verantwoordelijkheid, dat de CE 0123-gemarkeerde producten voldoen aan de essentiële vereisten (Bijlage I) van de Richtlijn Medische Hulpmiddelen 93/42 / EEG.

Verklaring uitsluitend gebaseerd op bijlage II (4). Indeling volgens regel 6, bijlage IX.

Toegepaste normen: ASTM D3577-19, 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 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, 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

Aangewezen instantie: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EC Certificate No.: G1 088308 0018 Rev. 00

Uitgegeven op: Singapore, 2024-01-10 **Geldig tot:** 2026-01-09

DECLARACIÓN DE CONFORMIDAD

DIRECTIVA DE PRODUCTOS MEDICINALES 93/42/EWG

Fabricante

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

Representante de la UE

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

El presente certificado es válido para los siguientes productos:

Guante de operación estéril para un solo uso
Clasificación: Clase IIa según la Directiva de Productos Medicinales 93/42/EEC

sempermed supreme (USA)

Tamaños	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Número de artículo	822751527	822751607	822751627	822751707	822751727	822751807	822751827	822751907
	3000006119	3000006120	3000006121	3000006122	3000006123	3000006124	3000006125	3000006126

Por la presente confirmamos bajo nuestra exclusiva responsabilidad que los productos con marcado CE 0123 cumplen con los requisitos esenciales (Anexo I) de la Directiva 93/42/CEE sobre productos sanitarios.

Declaración basada en el anexo II, excluido el punto 4. Clasificación según la regla 6, anexo IX

Normas aplicadas: ASTM D3577-19, 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 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, 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

Organismo notificado: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EC Certificate No.: G1 088308 0018 Rev. 00

Expedido el: Singapore, 2024-01-10 **Válido hasta:** 2026-01-09

DECLARAÇÃO DE CONFORMIDADE

DIRETIVA 93/42/CEE SOBRE DISPOSITIVOS MÉDICOS

Fabricante

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

Representante da UE

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

Este certificado é válido para os seguintes produtos:

Luva cirúrgica estéril para uso único
Classificação: Classe IIa de acordo com a Diretiva de Dispositivos Médicos 93/42/CEE

sempermed supreme (USA)

Tamanhos	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Números de artigo	822751527	822751607	822751627	822751707	822751727	822751807	822751827	822751907
	3000006119	3000006120	3000006121	3000006122	3000006123	3000006124	3000006125	3000006126

Declaramos desta forma, sob a nossa exclusiva responsabilidade, que os produtos com a marca CE 0123 estão em conformidade com os requisitos essenciais (anexo I) da Diretriz de Dispositivos Médicos 93/42/CEE.

Declaração baseada no anexo II excluindo (4). Classificação de acordo com a regra 6, anexo IX.

Normas aplicadas: ASTM D3577-19, 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 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, 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

Organismo nomeado: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EC Certificate No.: G1 088308 0018 Rev. 00

Emitido em: Singapore, 2024-01-10 **Válido até:** 2026-01-09

DEKLARATON OM ÖVERENSSTÄMMELSE

DIREkTIV 93/42/EEC MEDICINTEKNISKA PRODUKTER

Tillverkare

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

Behörig representant hos EU

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

Detta certifikat gäller följande produkt:

Steril kirurgihandske för engångsanvändning
Klassificering: Klass Ia enlligt EU-direktiv för medicintek-niska produkter (MD) 93/42/EEC

sempermed supreme (USA)

Storlekar	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Artikelnummer	822751527	822751607	822751627	822751707	822751727	822751807	822751827	822751907
	3000006119	3000006120	3000006121	3000006122	3000006123	3000006124	3000006125	3000006126

Vi förklarar härmed under eget exklusivt ansvar att ovan beskrivna, CE 0123-markerade produkt stämmer överens med erforderliga krav (Bilaga I) i direktivet för medicinska produkter 93/42/EEC.

Deklaration enligt Bilaga II, (4) undantagen. Klassifiering enligt 6, Bilaga IX.

Tillämpade standarder: ASTM D3577-19, 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 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, 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

Angiven myndighet: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EC Certificate No.: G1 088308 0018 Rev. 00

Daterad : Singapore, 2024-01-10 **Giltig till:** 2026-01-09

KONFORMITETSERKLÆRING

DIREKTIV 93/42/EØF OM MEDICINSK UDSTYR

Producent

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

EU-befuldmægtigede

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

Dette certifikat er gyldigt for følgende produkter:

Steril operationshandske til engangsbrug
Klassificering: Klasse IIa jævnfør 93/42/EØF-retningslinjerne for medicinsk udstyr

sempermed supreme (USA)

Størrelser	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Artikelnumre	822751527	822751607	822751627	822751707	822751727	822751807	822751827	822751907
	3000006119	3000006120	3000006121	3000006122	3000006123	3000006124	3000006125	3000006126

Vi bekræfter hermed under fuldt ansvar, at de ovenfor nævnte CE 0123-mærkede produkter stemmer overens med med de grundliggende krav (bilag I) i retningslinjerne for medicinsk udstyr 93/42/EØF.

Forklaring baseret på bilag II exklusiv (4). Klassificering jævnfør regel 6, bilag IX.

Anvendte standarder: ASTM D3577-19, 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 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, 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

Det nævnte sted: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EC Certificate No.: G1 088308 0018 Rev. 00

Udstedt den: Singapore, 2024-01-10 **Gyldig til:** 2026-01-09

KONFORMITETSERKLÆRING

DIREKTIV FOR MEDISINSK UTSTYR 93/42/EØS

Produsent

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

Autorisert representant i EU

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

Dette sertifikatet er gyldig for følgende produkter:

Steril operasjonshanske for engangsbruk
Klassifisering: Klasse IIa i henhold til Direktiv for medisinsk utstyr 93/42/EØS

sempermed supreme (USA)

Størrelser	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Artikkelnumre	822751527	822751607	822751627	822751707	822751727	822751807	822751827	822751907
	3000006119	3000006120	3000006121	3000006122	3000006123	3000006124	3000006125	3000006126

Vi erklærer herved under eneansvar at det CE 0123-merkede produktet oppfyller de grunnleggende kravene (Vedlegg I) i Direktivet for medisinsk utstyr 93/42/EØS.

Erklæring basert på Vedlegg II unntatt (4). Klassifisering i henhold til Regel nr. 6, Vedlegg IX.

Relevante standarder: ASTM D3577-19, 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 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, 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

Teknisk kontrollorgan: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EC Certificate No.: G1 088308 0018 Rev. 00

Utstedt den: Singapore, 2024-01-10 **Gyldig til:** 2026-01-09

VAATIMUSTENMUKAISUUSVAKUUTUS

LÄÄKINNÄLLISIÄ LAITTEITA KOSKEVA DIREKTIIVI 93/42/ETY

Valmistaja

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

EU:n valtuutettu edustaja

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

Tämä sertifikaatti koskee seuraavia tuotteita:

Kertakäyttöinen steriili leikkauskäsine
Luokitus: Luokka IIa lääkinnällisiä laitteita koskevan direktiivin 93/42/ETY mukaisesti

sempermed supreme (USA)

Koot	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Tuotenumerot	822751527	822751607	822751627	822751707	822751727	822751807	822751827	822751907
	3000006119	3000006120	3000006121	3000006122	3000006123	3000006124	3000006125	3000006126

Täten vahvistamme yksinomaisella vastuullamme, että CE 0123-merkityt tuotteet vastaavat lääkinnällisiä laitteita koskevan direktiivin 93/42/ETY mukaisia perustavanlaatuisia vaatimuksia (liite I).

Selvitys perustuu liitteeseen II, lukuun ottamatta (4). Luokittelu liitteen IX, säännön 6 mukaan

Sovelletut standardit: ASTM D3577-19, 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 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, 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

Ilmoitettu laitos: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EC Certificate No.: G1 088308 0018 Rev. 00

Laadittu : Singapore, 2024-01-10 **Voimassa (asti):** 2026-01-09

ATITIKTIES DEKLARACIJA

DIREKTYVA DĖL MEDICINOS PRIETAISŲ 93/42/EEB

Gamintojas

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

ES įgaliotas asmuo

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

Šis sertifikatas galioja toliau nurodytiems produktams:

Sterilios vienkartinio naudojimo operacinės pirštinės
Klasifikacija: IIa klasė pagal direktyvą dėl medicinos prietaisų 93/42/EEB

sempermed supreme (USA)

Dydžiai	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Prekių numeriai	822751527	822751607	822751627	822751707	822751727	822751807	822751827	822751907
	3000006119	3000006120	3000006121	3000006122	3000006123	3000006124	3000006125	3000006126

Prisiimdami visą atsakomybę šiuo dokumentu patvirtiname, kad CE 0123 paženklinti produktai atitinka svarbiausius direktyvos dėl medicinos prietaisų 93/42/EEB reikalavimus (I priedas).

Paaiškinimas remiasi tik II priedu (4). Klasifikacija pagal IX priedo 6 taisyklę.

Taikomi standartai: ASTM D3577-19, 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 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, 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

Notifikuotoji įstaiga: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EC Certificate No.: G1 088308 0018 Rev. 00

Išduota : Singapore, 2024-01-10 **Galioja iki:** 2026-01-09

ATBILSTĪBAS DEKLARĀCIJA

MEDICĪNAS IERĪČU DIREKTĪVA 93/42/EEK

Likumīgais ražotājs

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

Pilnvarotais pārstāvis ES

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

Šis sertifikāts ir derīgs šādam produktam:

Sterili ķirurģiskie cimdi vienreizējai lietošanai
Klasifikācija: IIa klase saskaņā ar medicīnas ierīču direktīvu 93/42/EEK

sempermed supreme (USA)

Izmēri	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Artikula numurs	822751527	822751607	822751627	822751707	822751727	822751807	822751827	822751907
	3000006119	3000006120	3000006121	3000006122	3000006123	3000006124	3000006125	3000006126

Ar šo mēs apliecinām, ka iepriekš aprakstītais produkts ar CE 0123 marķējumu atbilst medicīnas ierīču 93/42/EEK direktīvas pamatprasībām (I pielikums).

Deklarācija, pamatojoties uz II pielikumu, izņemot (4). Klasifikācija saskaņā ar IX pielikuma 6. noteikumu.

Piemērotie standarti: ASTM D3577-19, 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 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, 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

Pilnvarotā iestāde: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EC Certificate No.: G1 088308 0018 Rev. 00

Izdots : Singapore, 2024-01-10 **Derīgs līdz:** 2026-01-09

VASTAVUSDEKLARATSIOON

MEDITSIINITOODETE DIREKTIIV 93/42/EMÜ

Tootja

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

Volitatud esindaja EL-is

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

See sertifikaat kehtib järgmistele toodetele:

Steriilne kaitsekinnas ühekordseks kasutuseks
Klassifikatsioon: IIa klass kooskõlas meditsiinitoodete direktiiviga 93/42/EMÜ

sempermed supreme (USA)

Suurused	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Tootenumbrid	822751527	822751607	822751627	822751707	822751727	822751807	822751827	822751907
	3000006119	3000006120	3000006121	3000006122	3000006123	3000006124	3000006125	3000006126

Kinnitame oma ainuvastutusel, et CE 0123-märgisega tooted on kooskõlas meditsiinitoodete direktiivi 93/42/EMÜ peamiste nõuetega (I lisa).

Deklaratsioon põhineb II lisal, välja arvatud punkt 4. Klassifikatsioon kooskõlas IX lisa 6. reegliga.

Kohaldatud normid: ASTM D3577-19, 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 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, 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

Teavitatud asutus: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EC Certificate No.: G1 088308 0018 Rev. 00

Välja andmise aeg : Singapore, 2024-01-10 **Kehtivusaeg:** 2026-01-09

PROHLÁŠENÍ O SHODĚ

SMĚRNICE O ZDRAVOTNICKÝCH PROSTŘEDCÍCH 93/42/EHS

Výrobce

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

EU zplnomocněný zástupce

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

Tento certifikát je platný pro následující produkty:

Sterilní operační rukavice pro jednorázové použití
Klasifikace Třída IIa podle směrnice o zdravotnických prostředcích 93/42/EEC

sempermed supreme (USA)

Velikosti	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Číslo produktu	822751527	822751607	822751627	822751707	822751727	822751807	822751827	822751907
	3000006119	3000006120	3000006121	3000006122	3000006123	3000006124	3000006125	3000006126

Tímto potvrzujeme s výlučnou odpovědností, že produkty označené CE 0123 souhlasí se základními požadavky (příloha I) směrnice o zdravotnických prostředcích 93/42/EHS.

Vysvětlení se zakládají na příloze II včetně (4). klasifikace podle pravidla 6, příloha IX.

Použité normy: ASTM D3577-19, 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 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, 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

Uvedená místa: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EC Certificate No.: G1 088308 0018 Rev. 00

Vystaveno dne: Singapore, 2024-01-10 **Platné do:** 2026-01-09

VYHLÁSENIE O ZHODE

SMERNICA 93/42/EHS EURÓPSKEHO PARLAMENTU A RADY o zdravotníckych pomôckach

Výrobca

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

Splnomocnenec pre EÚ

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

Tento certifikát je platný pre nasledujúce body:

Sterilné operačné rukavice na jedno použitie
Klasifikácia: Trieda IIa podľa smernice 93/42/EHS o zdravotníckych pomôckach

sempermed supreme (USA)

Veľkosti	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Výrobné čísla	822751527	822751607	822751627	822751707	822751727	822751807	822751827	822751907
	3000006119	3000006120	3000006121	3000006122	3000006123	3000006124	3000006125	3000006126

Týmto vo svojej výhradnej zodpovednosti potvrdzujeme, že výrobky označené symbolom CE 0123 sú v súlade so základnými požiadavkami (Príloha I) Nariadenia 93/42/EHS o zdravotníckych pomôckach.

Vysvetlenie sa zakladá na prílohe II okrem (4). Klasifikácia podľa Pravidla 6, prílohy IX.

Súvisiace normy: ASTM D3577-19, 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 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, 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

Menovaná pozícia: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EC Certificate No.: G1 088308 0018 Rev. 00

Vyhotovené dňa: Singapore, 2024-01-10 **Platné do:** 2026-01-09

MEGFELELŐSÉGI NYILATKOZAT

ORVOSTECHNIKAI ESZKÖZÖKRŐL SZÓLÓ 93/42/EGK IRÁNYELV

Gyártó

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

EU-meghatalmazott

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

Ez a tanúsítvány a következő termékekre érvényes:

Egyszer használatos, steril műtős kesztyű
Osztályozás: IIa. osztály az orvostechnikai eszközökről szóló 93/42/EGK irányelv szerint

sempermed supreme (USA)

Méretek	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Cikkszámok	822751527	822751607	822751627	822751707	822751727	822751807	822751827	822751907
	3000006119	3000006120	3000006121	3000006122	3000006123	3000006124	3000006125	3000006126

Ezennel kizárólagos felelősségünk mellett kijelentjük, hogy a CE 0123 jelzésű termékek megfelelnek az orvostechnikai eszközökről szóló 93/42/EWG irányelv alapvető előírásainak.

Magyarázat a II. mellékleten alapszik, a 4. bekezdést kivéve Osztályozás a IX. melléklet 6. szabálya szerint

Alkalmazott szabványok: ASTM D3577-19, 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 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, 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

Bejelentett szervezet: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EC Certificate No.: G1 088308 0018 Rev. 00

Kelt : Singapore, 2024-01-10 **Érvényes:** 2026-01-09

IZJAVA O SKLADNOSTI

DIREKTIVA O MEDICINSKIH PRIPOMOČKIH 93/42/EGS

Proizvajalec

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

Pooblaščen zastopnik EU

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

To potrdilo velja za naslednje izdelke:

Sterilne kirurške rokavice za enkratno uporabo
Klasifikacija: Razred IIa v skladu z Direktivo o medicinskih pripomočkih 93/42/EGS

sempermed supreme (USA)

Velikosti	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Številke izdelkov	822751527	822751607	822751627	822751707	822751727	822751807	822751827	822751907
	3000006119	3000006120	3000006121	3000006122	3000006123	3000006124	3000006125	3000006126

S to izključno odgovornostjo izjavljamo, da so izdelki z oznako CE 0123 v skladu z bistvenimi zahtevami (Priloga I) Direktive za medicinske pripomočke 93/42/EGS.

Izjava, ki temelji na Prilogi II, razen (4). Razvrstitev v skladu s Pravilom 6, Priloga IX.

Uporabljeni standardi: ASTM D3577-19, 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 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, 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

Priglašeni organ: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EC Certificate No.: G1 088308 0018 Rev. 00

Izdano dne: Singapore, 2024-01-10 **Veljavno do:** 2026-01-09

IZJAVA O SUKLADNOSTI

DIREKTIVA O MEDICINSKIM PROIZVODIMA 93/42/EEZ

Proizvođač

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

Ovlašteni predstavnik u EU

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

Ovaj certifikat vrijedi za sljedeće proizvode:

Sterilne kirurške rukavice za jednokratnu uporabu
Klasifikacija: Klasa II.a prema Direktivi o medicinskim proizvodima 93/42/EEZ

sempermed supreme (USA)

Veličine	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Br. artikla	822751527	822751607	822751627	822751707	822751727	822751807	822751827	822751907
	3000006119	3000006120	3000006121	3000006122	3000006123	3000006124	3000006125	3000006126

Ovim putem izjavljujemo pod punom odgovornošću da su proizvodi s CE 0123 oznakom sukladni s bitnim zahtjevima (Prilog 1) Direktive o medicinskim proizvodima 93/42/EEZ.

Izjava se temelji na Prilogu II. ne uključujući (4). Klasifikacija prema pravilu 6, Prilog IX.

Primijenjene norme: ASTM D3577-19, 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 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, 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

Prijavljeno tijelo: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EC Certificate No.: G1 088308 0018 Rev. 00

Izdano dana: Singapore, 2024-01-10 **Vrijedi do:** 2026-01-09

DEKLARACJA ZGODNOŚCI

DYREKTYWA W SPRAWIE WYROBÓW MEDYCZNYCH 93/42/EWG

Producent

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

Autoryzowany przedstawiciel w UE

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

Niniejszy certyfikat obowiązuje w odniesieniu do następującego produktu:

Sterylne rękawice chirurgiczne jednorazowego użytku
Klasyfikacja: Klasa IIa zgodnie z dyrektywą 93/42/EWG w sprawie wyrobów medycznych

sempermed supreme (USA)

Rozmiary	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Numery artykułów	822751527	822751607	822751627	822751707	822751727	822751807	822751827	822751907
	3000006119	3000006120	3000006121	3000006122	3000006123	3000006124	3000006125	3000006126

Na własną odpowiedzialność oświadczamy niniejszym, że opisany powyżej produkt z oznakowaniem CE 0123 spełnia zasadnicze wymagania (załącznik I) dyrektywy w sprawie wyrobów medycznych 93/42/EWG.

Deklaracja oparta na załączniku II z wyłączeniem (4). Klasyfikacja jest zgodna z zasadą 6, załącznik IX.

Zastosowane normy: ASTM D3577-19, 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 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, 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

Jednostka notyfikowana: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EC Certificate No.: G1 088308 0018 Rev. 00

Data wydania: Singapore, 2024-01-10 **Data ważności:** 2026-01-09

DECLARAȚIE DE CONFORMITATE

DIRECTIVĂ PRIVIND PRODUSELE MEDICALE 93/42/CEE

Producător

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

Persoană împuternicită EU

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

Acest certificat este valabil pentru următoarele produse:

Mânușă sterilă de unică folosință pentru operații
clasificare: Clasa IIa conform directivei privind produsele medicale 93/42/CEE

sempermed supreme (USA)

mărimi	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
numerele de articole	822751527	822751607	822751627	822751707	822751727	822751807	822751827	822751907
	3000006119	3000006120	3000006121	3000006122	3000006123	3000006124	3000006125	3000006126

Prin prezenta confirmăm preluând toată responsabilitatea că produsele marcate CE 0123 corespund cerințelor de bază (anexa I) din directiva privind produsele medicale 93/42/CEE.

Declarația se bazează pe anexa II exclusiv (4). Clasificare conform regulii 6, anexa IX.

Normele aplicate: ASTM D3577-19, 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 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, 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

Organismul abilitat: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EC Certificate No.: G1 088308 0018 Rev. 00

Eliberat la data de: Singapore, 2024-01-10 **Valabil până în:** 2026-01-09

ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ

ΟΔΗΓΙΑ 93/42/ΕΟΚ ΠΕΡΙ ΙΑΤΡΟΤΕΧΝΟΛΟΓΙΚΩΝ ΠΡΟΪΟΝΤΩΝ

Κατασκευαστής	Εξουσιοδοτημένος αντιπρόσωπος στην ΕΕ
Semperit Investments Asia Pte. Ltd. **8 Jurong Town Hall Road,** **#29-03 to 06 The JTC Summit,** **Singapore 609434, Singapore** **sempermed@harpsglobal.com** **SRN: SG-MF-000001645**	**Semperit Technische Produkte Gesellschaft m.b.H.** **Triester Bundesstraße 26, 2632 Wimpassing, Austria** **sempermed@harpsglobal.com** **SRN: AT-AR-000000735**

Το παρόν πιστοποιητικό ισχύει για τα ακόλουθα προϊόντα:

Αποστειρωμένο χειρουργικό γάντι μιας χρήσης
Ταξινόμηση: Κατηγορία IIa σύμφωνα με την οδηγία 93/42/ΕΟΚ περί ιατροτεχνολογικών προϊόντων

sempermed supreme (USA)

Μεγέθη	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Αριθμοί προϊόντος	822751527	822751607	822751627	822751707	822751727	822751807	822751827	822751907
	3000006119	3000006120	3000006121	3000006122	3000006123	3000006124	3000006125	3000006126

Δια του παρόντος βεβαιώνουμε υπεύθυνα ότι τα προϊόντα με σήμανση CE 0123 ικανοποιούν τις βασικές απαιτήσεις (Παράρτημα I) της οδηγίας 93/42/ΕΟΚ περί ιατροτεχνολογικών προϊόντων.

Δήλωση βάσει του Παραρτήματος II, εξαιρουμένου του σημείου (4). Ταξινόμηση σύμφωνα με τον κανόνα 6, Παράρτημα IX.

Εφαρμοζόμενα πρότυπα: ASTM D3577-19, 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 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, 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

Κοινοποιημένος οργανισμός: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EC Certificate No.: G1 088308 0018 Rev. 00

Εκδόθηκε : Singapore, 2024-01-10 **Ισχύει έως:** 2026-01-09

ДЕКЛАРАЦИЯ ЗА СЪВМЕСТИМОСТ НА

ДИРЕКТИВА ЗА МЕДИЦИНСКИТЕ ПРОДУКТИ 93/42/EWG

Производител

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

Упълномощен представител в ЕС

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

Настоящият сертификат важи за следните продукти:

Стерилна операционна ръкавица за еднократна употреба
Класификация: Клас IIa съгл. Директивата за медицинските продукти 93/42/EEC

sempermed supreme (USA)

Размери	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Номера на артикулите	822751527	822751607	822751627	822751707	822751727	822751807	822751827	822751907
	3000006119	3000006120	3000006121	3000006122	3000006123	3000006124	3000006125	3000006126

С настоящето потвърждаваме при самостоятелна отговорност, че продуктите с маркировка CE 0123 съответстват на съществените изисквания (Анекс I) от Директивата за медицинските продукти 93/42/EWG.

Декларация на базата на Анекс II с изключение на (4). Класификация съгл. Правило 6, Приложение IX.

Приложими норми: ASTM D3577-19, 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 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, 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

Нотифициран орган: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EC Certificate No.: G1 088308 0018 Rev. 00

Издадено на: Singapore, 2024-01-10 **Важи до:** 2026-01-09

UYGUNLUK BEYANI

TIBBİ CİHAZ DİREKTİFİ 93/42/AET

Üretici

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

AB'de yetkili temsilci

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

Bu sertifika aşağıdaki ürün için geçerlidir:

Tek kullanımlık steril operasyon eldiveni
Sınıflandırma: 93/42/EEC sayılı Tıbbi Ürün Direktifi uyarınca Sınıf IIa

sempermed supreme (USA)

Boyutlar	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Ürün numaraları	822751527	822751607	822751627	822751707	822751727	822751807	822751827	822751907
	3000006119	3000006120	3000006121	3000006122	3000006123	3000006124	3000006125	3000006126

Yukarıda açıklanan CE 0123 işaretli ürünün 93/42/AET sayılı tıbbi cihazlara ilişkin direktifin esas koşullarına (Ek I) uygun olduğunu tek sorumluluğumuzda beyan ederiz.

(4) hariç Ek II'ye dayanan beyanname. Ek IX, kural 6 uyarınca sınıflandırma.

Uygulamalı standartlar: ASTM D3577-19, 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 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, 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

Onaylanmış kuruluş: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EC Certificate No.: G1 088308 0018 Rev. 00

Veriliş tarihi: Singapore, 2024-01-10 **Son geçerlilik tarihi:** 2026-01-09