

EU DECLARATION OF CONFORMITY

MEDICAL DEVICE REGULATION (EU) 2017/745
 PERSONAL PROTECTIVE EQUIPMENT REGULATION (EU) 2016/425

Legal Manufacturer

HARPS Investment Asia Pte. Ltd.
 #08-10A Marina One West Tower,
 9 Straits View, Singapore 018937, Singapore
 sempermed@harpsglobal.com
 SRN: SG-MF-000001645

Authorized representative in the EU

HARPS Europe GmbH
 Wiedner Guertel 9-13
 1100 Wien, Austria
 sempermed@harpsglobal.com
 SRN: AT-AR-000040870

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: 9001570NOT-063GB-N-3DY

semperguard Xpert

Sizes	X-Small	Small	Medium	Large	X-Large	XX-Large
Article codes	-	3000016078	3000016079	3000016080	3000016081	3000016082

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 (2023), ASTM D6319-19 (2023) or ASTM D5250-19 (2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A2:2024, EN 455-2:2024, EN 455-3:2023, 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 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

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. 2777/11462-04/E01-01 issued by:

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

The products are subject to the procedure set out in Annex VII (Module C2) of Regulation (EU) 2016/425 under the supervision of **SATRA Technology Europe Ltd, ID No. 2777**
 Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Applied standards: EN 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



Birgit Sebauer
 Person Responsible for Regulatory Compliance



Larissa Rieger
 Head of Product Management

Issued: 2025-10-29

Expires: 2027-10-28

Version: 003

EU-KONFORMITÄTSERKLÄRUNG

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

Hersteller

HARPS Investment Asia Pte. Ltd.
#08-10A Marina One West Tower,
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EU-Bevollmächtigter

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SRN: AT-AR-000040870

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

Basis-UDI-DI: 9001570NOT-063GB-N-3DY

semperguard Xpert

Größen	X-Small	Small	Medium	Large	X-Large	XX-Large
Artikelnummern	-	3000016078	3000016079	3000016080	3000016081	3000016082

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 (2023), ASTM D6319-19 (2023) or ASTM D5250-19 (2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A2:2024, EN 455-2:2024, EN 455-3:2023, 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 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

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. 2777/11462-04/E01-01 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



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Ausgestellt am: 2025-10-29

Gültig bis: 2027-10-28

Version: 003

DÉCLARATION UE DE CONFORMITÉ

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

Fabricant

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Représentant UE

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SRN: AT-AR-000040870

Ce certificat est valable pour les produits suivants :

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

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

IUD-ID de base: 9001570NOT-063GB-N-3DY

semperguard Xpert

Tailles	X-Small	Small	Medium	Large	X-Large	XX-Large
Numéros d'article	-	3000016078	3000016079	3000016080	3000016081	3000016082

Par la présente, nous déclarons sous notre propre responsabilité que les produits portant le symbole CE sont conformes aux exigences du 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 (2023), ASTM D6319-19 (2023) or ASTM D5250-19 (2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A2:2024, EN 455-2:2024, EN 455-3:2023, 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 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

Par la présente, nous déclarons sous notre propre responsabilité que les produits portant le symbole CE mentionnés ci-dessus sont conformes aux dispositions essentielles du 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 2777/11462-04/E01-01 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) du 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



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Délivré le : 2025-10-29

Valable jusqu'au :

2027-10-28

Version: 003

DICHIARAZIONE DI CONFORMITÀ UE

REGOLAMENTO SUL DISPOSITIVO MEDICO (UE) 2017/745
REGOLAMENTO (UE) 2016/425 DELL'APPARECCHIATURA DI PROTEZIONE INDIVIDUALE

Produttore

HARPS Investment Asia Pte. Ltd.
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Rappresentante autorizzato nell'UE

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Wiedner Guertel 9-13
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sempermed@harpsglobal.com
SRN: AT-AR-000040870

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

UDI-DI di base: 9001570NOT-063GB-N-3DY

semperguard Xpert

Misure	X-Small	Small	Medium	Large	X-Large	XX-Large
Codici articolo	-	3000016078	3000016079	3000016080	3000016081	3000016082

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 (2023), ASTM D6319-19 (2023) or ASTM D5250-19 (2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A2:2024, EN 455-2:2024, EN 455-3:2023, 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 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

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. 2777/11462-04/E01-01 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



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Rilasciato : 2025-10-29

Scade: 2027-10-28

Version: 003

EU-CONFORMITEITSVERKLARING

VERORDENING MEDISCHE PRODUCTEN (EU) 2017/745
VERORDENING (EU) 2016/425 BETREFFENDE PERSOONLIJKE BESCHERMENDE UITRUSTING

Fabrikant

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Gemachtigde EU

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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: 9001570NOT-063GB-N-3DY

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Maten	X-Small	Small	Medium	Large	X-Large	XX-Large
Artikelnummers	-	3000016078	3000016079	3000016080	3000016081	3000016082

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 (2023), ASTM D6319-19 (2023) or ASTM D5250-19 (2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A2:2024, EN 455-2:2024, EN 455-3:2023, 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 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

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.2777/11462-04/E01-01 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



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Uitgegeven op: 2025-10-29

Geldig tot: 2027-10-28

Versie: 003

DECLARACIÓN UE DE CONFORMIDAD

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

Fabricante

HARPS Investment Asia Pte. Ltd.
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Representante de la UE

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SRN: AT-AR-000040870

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

UDI-DI básico: 9001570NOT-063GB-N-3DY

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Tamaños	X-Small	Small	Medium	Large	X-Large	XX-Large
Número de artículo	-	3000016078	3000016079	3000016080	3000016081	3000016082

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 (2023), ASTM D6319-19 (2023) or ASTM D5250-19 (2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A2:2024, EN 455-2:2024, EN 455-3:2023, 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 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

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. 2777/11462-04/E01-01 expedido por:

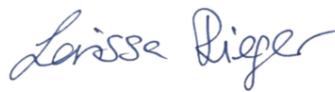
SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

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



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Expedido el: 2025-10-29

Válido hasta: 2027-10-28

Versión: 003

DECLARAÇÃO DE CONFORMIDADE UE

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

Fabricante

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Representante da UE

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SRN: AT-AR-000040870

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

UDI-DI básico: 9001570NOT-063GB-N-3DY

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Tamanhos	X-Small	Small	Medium	Large	X-Large	XX-Large
Números de artigo	-	3000016078	3000016079	3000016080	3000016081	3000016082

Declaramos desta forma, sob a nossa exclusiva responsabilidade, que os produtos com a marca CE estão em conformidade com os requisitos do 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 (2023), ASTM D6319-19 (2023) or ASTM D5250-19 (2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A2:2024, EN 455-2:2024, EN 455-3:2023, 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 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

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 2777/11462-04/E01-01 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



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Emitido em: 2025-10-29

Válido até: 2027-10-28

Versão: 003

EU-FÖRSÄKRAN OM ÖVERENSSTÄMMELSE

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

Tillverkare

HARPS Investment Asia Pte. Ltd.
#08-10A Marina One West Tower,
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sempermed@harpsglobal.com
SRN: SG-MF-000001645

Behörig representant hos EU

HARPS Europe GmbH
Wiedner Guertel 9-13
1100 Wien, Austria
sempermed@harpsglobal.com
SRN: AT-AR-000040870

Detta certifikat gäller följande produkt:

Icke-steril inspektions- och skyddshandske för engångsanvändning

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

Grundläggande UDI-DI: 9001570NOT-063GB-N-3DY

semperguard Xpert

Storlekar	X-Small	Small	Medium	Large	X-Large	XX-Large
Artikelnummer	-	3000016078	3000016079	3000016080	3000016081	3000016082

Vi förklarar härmed under eget exklusivt ansvar att ovan beskrivna, CE-märkade produkt stämmer överens med kraven i EU-förordningen för medicintekniska produkter 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 (2023), ASTM D6319-19 (2023) or ASTM D5250-19 (2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A2:2024, EN 455-2:2024, EN 455-3:2023, 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 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

Vi förklarar härmed under eget exklusivt ansvar att ovan beskrivna, CE-märkade 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 nummer 2777/11462-04/E01-01 daterad av:

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

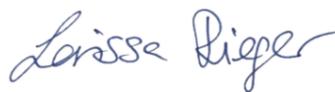
och är föremål för den procedur som beskrivs i Bilaga VII (Modul C2) till EU-förordningen 2016/425 under uppsikt av

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



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Daterad : 2025-10-29

Giltig till:

2027-10-28

Version: 003

EU-OVERENSSTEMMELSESERKLÆRING

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

Producent

HARPS Investment Asia Pte. Ltd.
#08-10A Marina One West Tower,
9 Straits View, Singapore 018937, Singapore
sempermed@harpsglobal.com
SRN: SG-MF-000001645

EU-befuldmægtigede

HARPS Europe GmbH
Wiedner Guertel 9-13
1100 Wien, Austria
sempermed@harpsglobal.com
SRN: AT-AR-000040870

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

Grundlæggende UDI-DI: 9001570NOT-063GB-N-3DY

semperguard Xpert

Størrelser	X-Small	Small	Medium	Large	X-Large	XX-Large
Artikelnumre	-	3000016078	3000016079	3000016080	3000016081	3000016082

Vi bekræfter hermed under fuldt ansvar, at de ovenfor nævnte CE-mærkede produkter stemmer overens med kravene 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 (2023), ASTM D6319-19 (2023) or ASTM D5250-19 (2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A2:2024, EN 455-2:2024, EN 455-3:2023, 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 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

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.2777/11462-04/E01-01 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



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Udstedt den: 2025-10-29

Gyldigt til: 2027-10-28

Version: 003

EU-SAMSVARSKLÆRING

EU-FORORDNING OM MEDISINSK UTSTYR 2017/745
EU-FORORDNING OM PERSONLIG VERNEUTSTYR 2016/425

Juridisk produsent

HARPS Investment Asia Pte. Ltd.
#08-10A Marina One West Tower,
9 Straits View, Singapore 018937, Singapore
sempermed@harpsglobal.com
SRN: SG-MF-000001645

Autorisert representant i EU

HARPS Europe GmbH
Wiedner Guertel 9-13
1100 Wien, Austria
sempermed@harpsglobal.com
SRN: AT-AR-000040870

Dette sertifikatet er gyldig for følgende produkt:

Ikke-steril undersøkelses- og beskyttelseshanske for engangsbruk

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

Basic UDI-DI: 9001570NOT-063GB-N-3DY

semperguard Xpert

Størrelser	X-Small	Small	Medium	Large	X-Large	XX-Large
Artikkelnumre	-	3000016078	3000016079	3000016080	3000016081	3000016082

Vi erklærer herved under eneansvar at det CE-merkede produktet oppfyller kravene i EU-forordningen om medisinsk utstyr 2017/745.

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

Anvendte standarder: ASTM D3578-19 (2023), ASTM D6319-19 (2023) or ASTM D5250-19 (2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A2:2024, EN 455-2:2024, EN 455-3:2023, 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 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

Vi erklærer herved under eneansvar at det CE-merkede produktet som er nevnt ovenfor oppfyller de relevante bestemmelsene i EU-forordning nr. 2016/425 om personlig verneutstyr og er gjenstand for EU-typeprøvesertifikat nr. 2777/11462-04/E01-01 utstedt: av:

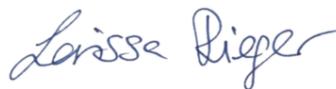
SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Produktet er gjenstand for prosedyren som er beskrevet i Vedlegg VII (Modul C2) i EU-forordning nr. 2016/425 under tilsyn av
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



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Utstedt: 2025-10-29

Utløper: 2027-10-28

Versjon: 003

EU-VAATIMUSTENMUKAISUUSVAKUUTUS

LÄÄKINNÄLLISIÄ LAITTEITA KOSKEVA ASETUS (EU) 2017/745
HENKILÖNSUOJAIMISTA ANNETTU ASETUS (EU) 2016/425

Valmistaja

HARPS Investment Asia Pte. Ltd.
#08-10A Marina One West Tower,
9 Straits View, Singapore 018937, Singapore
sempermed@harpsglobal.com
SRN: SG-MF-000001645

EU:n valtuutettu edustaja

HARPS Europe GmbH
Wiedner Guertel 9-13
1100 Wien, Austria
sempermed@harpsglobal.com
SRN: AT-AR-000040870

Tämä sertifiikaatti koskee seuraavia tuotteita:

Kertakäyttöinen ei-steriili tutkimus- ja suojakäsine

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

Yksilöllisen UDI-DI: 9001570NOT-063GB-N-3DY

semperguard Xpert

Koot	X-Small	Small	Medium	Large	X-Large	XX-Large
Tuotenumerot	-	3000016078	3000016079	3000016080	3000016081	3000016082

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.

Sovelletut standardit: ASTM D3578-19 (2023), ASTM D6319-19 (2023) or ASTM D5250-19 (2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A2:2024, EN 455-2:2024, EN 455-3:2023, 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 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

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 2777/11462-04/E01-01 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

Sovelletut 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



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Laadittu : 2025-10-29

Voimassa (asti):

2027-10-28

Versio: 003

ES ATITIKTIES DEKLARACIJA

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

Gamintojas

HARPS Investment Asia Pte. Ltd.
#08-10A Marina One West Tower,
9 Straits View, Singapore 018937, Singapore
sempermed@harpsglobal.com
SRN: SG-MF-000001645

ES įgaliotas asmuo

HARPS Europe GmbH
Wiedner Guertel 9-13
1100 Wien, Austria
sempermed@harpsglobal.com
SRN: AT-AR-000040870

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

Bazinis UDI-DI: 9001570NOT-063GB-N-3DY

semperguard Xpert

Dydžiai	X-Small	Small	Medium	Large	X-Large	XX-Large
Prekių numeriai	-	3000016078	3000016079	3000016080	3000016081	3000016082

Prisiimdami visą atsakomybę šiuo dokumentu patvirtiname, kad CE paženklinėti 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 (2023), ASTM D6319-19 (2023) or ASTM D5250-19 (2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A2:2024, EN 455-2:2024, EN 455-3:2023, 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 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

Prisiimdami visą atsakomybę, šiuo dokumentu patvirtiname, kad anksčiau paminėti CE paženklinėti produktai atitinka svarbiausius reglamentą dėl asmeninių apsaugos priemonių (ES) 2016/425 reikalavimus ir yra ES tipo tyrimo sertifikato Nr. objektas. 2777/11462-04/E01-01 išduota :

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

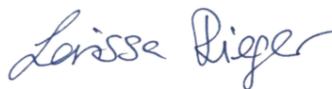
Produktai yra metodo objektas pagal reglamentą (ES) 2016/425 VII priedą (modulis C2) prižiūrint

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



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Išduota : 2025-10-29

Galioja iki: 2027-10-28

Versija: 003

ES ATBILSTĪBAS DEKLARĀCIJA

MEDICĪNAS IERĪČU REGULĀ (ES) 2017/745
REGULA (ES) 2016/425 PAR INDIVIDUĀLAJĪEM AIZSARDZĪBAS LĪDZEKĻIEM

Likumīgais ražotājs

HARPS Investment Asia Pte. Ltd.
#08-10A Marina One West Tower,
9 Straits View, Singapore 018937, Singapore
sempermed@harpsglobal.com
SRN: SG-MF-000001645

Pilnvarotais pārstāvis ES

HARPS Europe GmbH
Wiedner Guertel 9-13
1100 Wien, Austria
sempermed@harpsglobal.com
SRN: AT-AR-000040870

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

Pamata UDI-DI: 9001570NOT-063GB-N-3DY

semperguard Xpert

Izmēri	X-Small	Small	Medium	Large	X-Large	XX-Large
Artikula numurs	-	3000016078	3000016079	3000016080	3000016081	3000016082

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 (2023), ASTM D6319-19 (2023) or ASTM D5250-19 (2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A2:2024, EN 455-2:2024, EN 455-3:2023, 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 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

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. 2777/11462-04/E01-01 izdots :

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

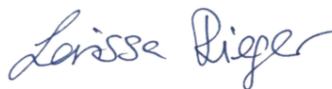
Uz produktiem attiecas Regulas (ES) 2016/425 VII pielikumā (C2 modulis) noteiktā procedūra, atbilstības uzraugs:

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



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Izdots : 2025-10-29

Derīgs līdz: 2027-10-28

Versija: 003

ELI VASTAVUSDEKLARATSIOON

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

Seaduslik tootja

HARPS Investment Asia Pte. Ltd.
#08-10A Marina One West Tower,
9 Straits View, Singapore 018937, Singapore
sempermed@harpsglobal.com
SRN: SG-MF-000001645

Volitatud esindaja EL-is

HARPS Europe GmbH
Wiedner Guertel 9-13
1100 Wien, Austria
sempermed@harpsglobal.com
SRN: AT-AR-000040870

See sertifikaat kehtib järgmistele toodetele:

Mittesteriilne läbivaatus- ja kaitsekinnas ühekordseks kasutuseks

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

Põhi-UDI-DI: 9001570NOT-063GB-N-3DY

semperguard Xpert

Suurused	X-Small	Small	Medium	Large	X-Large	XX-Large
Tootenumbrid	-	3000016078	3000016079	3000016080	3000016081	3000016082

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

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

Kohaldatud normid: ASTM D3578-19 (2023), ASTM D6319-19 (2023) or ASTM D5250-19 (2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A2:2024, EN 455-2:2024, EN 455-3:2023, 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 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

Kinnitame oma ainuvastutusel, et eespool nimetatud CE-märgistusega toode on kooskõlas isikukaitsevahendite määruse (EL) 2016/425 põhisätetega ning on identne isikukaitsevahendiga, mille kohta on välja antud ELi tüübihindamistõend nr2777/11462-04/E01-01 välja andnud:

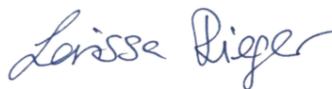
SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

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



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Välja antud : 2025-10-29

Aegub: 2027-10-28

Versioon: 003

EU PROHLÁŠENÍ O SHODĚ

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

Výrobce

HARPS Investment Asia Pte. Ltd.
#08-10A Marina One West Tower,
9 Straits View, Singapore 018937, Singapore
sempermed@harpsglobal.com
SRN: SG-MF-000001645

EU zplnomocněný zástupce

HARPS Europe GmbH
Wiedner Guertel 9-13
1100 Wien, Austria
sempermed@harpsglobal.com
SRN: AT-AR-000040870

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

Základní UDI-DI: 9001570NOT-063GB-N-3DY

semperguard Xpert

Velikosti	X-Small	Small	Medium	Large	X-Large	XX-Large
Číslo produktu	-	3000016078	3000016079	3000016080	3000016081	3000016082

Tímto potvrzujeme s výlučnou odpovědností, že produkty označené CE souhlasí s 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 (2023), ASTM D6319-19 (2023) or ASTM D5250-19 (2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A2:2024, EN 455-2:2024, EN 455-3:2023, 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 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

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.2777/11462-04/E01-01 vystaveno:

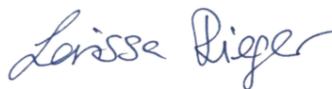
SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

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



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Vystaveno dne: 2025-10-29

Platné do: 2027-10-28

Verze: 003

EÚ VYHLÁSENIE O ZHODE

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

Výrobca

HARPS Investment Asia Pte. Ltd.
#08-10A Marina One West Tower,
9 Straits View, Singapore 018937, Singapore
sempermed@harpsglobal.com
SRN: SG-MF-000001645

Splnomocnenec pre EÚ

HARPS Europe GmbH
Wiedner Guertel 9-13
1100 Wien, Austria
sempermed@harpsglobal.com
SRN: AT-AR-000040870

Tento certifikát je platný pre nasledujúce body:

Nesterilné vyšetrovacie a ochranné rukavice na jedno použitie

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

Základný UDI-DI 9001570NOT-063GB-N-3DY

semperguard Xpert

Veľkosti	X-Small	Small	Medium	Large	X-Large	XX-Large
Výrobné čísla	-	3000016078	3000016079	3000016080	3000016081	3000016082

Týmto vo svojej výhradnej zodpovednosti potvrdzujeme, že výrobky označené symbolom CE sú v súlade s požiadavkami Nariadenia (EÚ) 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 (2023), ASTM D6319-19 (2023) or ASTM D5250-19 (2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A2:2024, EN 455-2:2024, EN 455-3:2023, 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 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

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 EÚ osvedčenia o typovej skúške č. 2777/11462-04/E01-01 vyhotovené :

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

Výrobky sú predmetom konania podľa dodatku VII (modul 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



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Vyhotovené dňa: 2025-10-29

Platné do: 2027-10-28

Verzia: 003

EU-MEGFELELŐSÉGI NYILATKOZAT

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

Gyártó

HARPS Investment Asia Pte. Ltd.
#08-10A Marina One West Tower,
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sempermed@harpsglobal.com
SRN: SG-MF-000001645

Meghatalmazott képviselő az EU-ban

HARPS Europe GmbH
Wiedner Guertel 9-13
1100 Wien, Austria
sempermed@harpsglobal.com
SRN: AT-AR-000040870

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

Alapvető UDI-DI: 9001570NOT-063GB-N-3DY

semperguard Xpert

Méret	X-Small	Small	Medium	Large	X-Large	XX-Large
Cikkszámok	-	3000016078	3000016079	3000016080	3000016081	3000016082

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

A nyilatkozat a IV. mellékleten alapul. Osztályozás a VIII. melléklet, 5. szabálya szerint. A megfelelőségi értékelés a II. mellékleten alapul.

Alkalmazott szabványok: ASTM D3578-19 (2023), ASTM D6319-19 (2023) or ASTM D5250-19 (2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A2:2024, EN 455-2:2024, EN 455-3:2023, 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 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

Ezennel kizárólagos felelősségünk mellett kijelentjük, hogy a fent említett CE-jelzésű termékek megfelelnek az egyéni védőeszközökről szóló 2016/425/EU rendelet vonatkozó rendelkezéseinek, és a következő számú EU-típusvizsgálati tanúsítvány vonatkozik rájuk:2777/11462-04/E01-01 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



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Kelt : 2025-10-29

Érvényes: 2027-10-28

Verzió: 003

IZJAVA EU O SKLADNOSTI

UREDBA O MEDICINSKIH PRIPOMOČKIH (EU) 2017/745
UREDBA ZA OSEBNO VAROVALNO OPREMO (EU) 2016/425

Proizvajalec

HARPS Investment Asia Pte. Ltd.
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sempermed@harpsglobal.com
SRN: SG-MF-000001645

Pooblaščenec zastopnik v EU

HARPS Europe GmbH
Wiedner Guertel 9-13
1100 Wien, Austria
sempermed@harpsglobal.com
SRN: AT-AR-000040870

To potrjuje velja za naslednji izdelek:

Nesterilne preiskovalne zaščitne rokavice za enkratno uporabo

Klasifikacija: Razred I v skladu z Uredbo o medicinskih pripomočkih (EU) 2017/745
Kategorija III v skladu z Uredbo OVO (EU) 2016/425

Osnovni UDI-DI: 9001570NOT-063GB-N-3DY

semperguard Xpert

Velikosti	X-Small	Small	Medium	Large	X-Large	XX-Large
Številke izdelkov	-	3000016078	3000016079	3000016080	3000016081	3000016082

S to izključno odgovornostjo izjavljamo, da zgoraj navedeni izdelki z oznako CE izpolnjujejo zahteve Uredbe za medicinske pripomočke (EU) 2017/745.

Izjava na podlagi Priloge IV. Razvrstitev v skladu s pravilom 5 Priloge VIII. Ocenjevanje skladnosti temelji na Prilogi II.

Uporabljeni standardi: ASTM D3578-19 (2023), ASTM D6319-19 (2023) or ASTM D5250-19 (2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A2:2024, EN 455-2:2024, EN 455-3:2023, 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 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

S to izključno odgovornostjo izjavljamo, da so zgoraj navedeni izdelki z oznako CE v skladu z veljavnimi zahtevami Uredbe (EU) 2016/425. za osebno varovalno opremo in so enaki osebnim zaščitni opremitvi, ki je predmet certifikata o EU-pregledu tipa št. 2777/11462-04/E01-01 izdano :

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

Izdelki so predmet postopka, opredeljenega v Prilogi 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



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Izdano dne: 2025-10-29

Veljavno do: 2027-10-28

Različica: 003

EU IZJAVA O SUKLADNOSTI

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

Proizvođač

HARPS Investment Asia Pte. Ltd.
#08-10A Marina One West Tower,
9 Straits View, Singapore 018937, Singapore
sempermed@harpsglobal.com
SRN: SG-MF-000001645

Ovlašteni predstavnik u EU

HARPS Europe GmbH
Wiedner Guertel 9-13
1100 Wien, Austria
sempermed@harpsglobal.com
SRN: AT-AR-000040870

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

Osnovni UDI-DI: 9001570NOT-063GB-N-3DY

semperguard Xpert

Veličine	X-Small	Small	Medium	Large	X-Large	XX-Large
Br. artikla	-	3000016078	3000016079	3000016080	3000016081	3000016082

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 (2023), ASTM D6319-19 (2023) or ASTM D5250-19 (2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A2:2024, EN 455-2:2024, EN 455-3:2023, 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 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

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.2777/11462-04/E01-01 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



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Izdano dana: 2025-10-29

Vrijedi do: 2027-10-28

Verzija: 003

DEKLARACJA ZGODNOŚCI UE

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

Producent

HARPS Investment Asia Pte. Ltd.
#08-10A Marina One West Tower,
9 Straits View, Singapore 018937, Singapore
sempermed@harpsglobal.com
SRN: SG-MF-000001645

Autoryzowany przedstawiciel w UE

HARPS Europe GmbH
Wiedner Guertel 9-13
1100 Wien, Austria
sempermed@harpsglobal.com
SRN: AT-AR-000040870

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: 9001570NOT-063GB-N-3DY

semperguard Xpert

Rozmiary	X-Small	Small	Medium	Large	X-Large	XX-Large
Numery artykułów	-	3000016078	3000016079	3000016080	3000016081	3000016082

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 (2023), ASTM D6319-19 (2023) or ASTM D5250-19 (2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A2:2024, EN 455-2:2024, EN 455-3:2023, 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 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

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 2777/11462-04/E01-01 data przez:

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

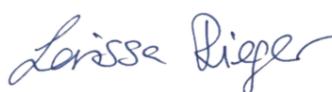
Produkty podlegają procedurze określonej w załączniku VII (moduł C2) rozporządzenia (UE) 2016/425 pod nadzorem

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



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Data wydania: 2025-10-29

Data ważności:

2027-10-28

Wersja: 003

DECLARAȚIA DE CONFORMITATE UE

REGULAMENTULUI PRIVIND PRODUSELE MEDICALE (UE) 2017/745
REGULAMENTULUI (UE) 2016/425 PENTRU ECHIPAMENTUL PERSONAL DE PROTECȚIE

Producător

HARPS Investment Asia Pte. Ltd.
#08-10A Marina One West Tower,
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SRN: SG-MF-000001645

Persoană împuternicită UE

HARPS Europe GmbH
Wiedner Guertel 9-13
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SRN: AT-AR-000040870

Acest certificat este valabil pentru următoarele produse:

Mănușă de consult și de protecție nesterilă de unică folosință

clasificare: Clasa I conform regulamentului (UE) 2017/745 privind produsele medicale
Categoría III conform regulamentului (UE) 2016/425 privind EPP

UDI-DI de bază: 9001570NOT-063GB-N-3DY

semperguard Xpert

mărimi	X-Small	Small	Medium	Large	X-Large	XX-Large
Numerele de articole	-	3000016078	3000016079	3000016080	3000016081	3000016082

Prin prezenta declarăm pe propria răspundere că produsele marcate CE corespund cerințelor din Regulamentul 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.

Standarde aplicate: ASTM D3578-19 (2023), ASTM D6319-19 (2023) or ASTM D5250-19 (2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A2:2024, EN 455-2:2024, EN 455-3:2023, 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 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

Prin prezenta declarăm pe propria răspundere că produsele marcate CE indicate mai sus corespund cerințelor Regulamentului (UE) 2016/425 pentru echipamente personale de protecție și acestea sunt obiectul certificării de tip CE nr. 2777/11462-04/E01-01 eliberat de către:

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

Standarde 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



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Eliberat la data de: 2025-10-29

Valabil până în:

2027-10-28

Versiune: 003

ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ ΕΕ

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

Κατασκευαστής

HARPS Investment Asia Pte. Ltd.
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SRN: SG-MF-000001645

Εξουσιοδοτημένος αντιπρόσωπος στην ΕΕ

HARPS Europe GmbH
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1100 Wien, Austria
sempermed@harpsglobal.com
SRN: AT-AR-000040870

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

Βασικό UDI-DI: 9001570NOT-063GB-N-3DY

semperguard Xpert

Μεγέθη	X-Small	Small	Medium	Large	X-Large	XX-Large
Αριθμοί προϊόντος	-	3000016078	3000016079	3000016080	3000016081	3000016082

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 (2023), ASTM D6319-19 (2023) or ASTM D5250-19 (2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A2:2024, EN 455-2:2024, EN 455-3:2023, 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 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

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. 2777/11462-04/Ε01-01 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



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Εκδόθηκε : 2025-10-29

Ισχύει έως:

2027-10-28

Εκδοχή: 003

ЕС ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ

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

Производител

HARPS Investment Asia Pte. Ltd.
#08-10A Marina One West Tower,
9 Straits View, Singapore 018937, Singapore
sempermed@harpsglobal.com
SRN: SG-MF-000001645

Упълномощен представител в ЕС

HARPS Europe GmbH
Wiedner Guertel 9-13
1100 Wien, Austria
sempermed@harpsglobal.com
SRN: AT-AR-000040870

Настоящият сертификат важи за следните продукти:

Нестерилна ръкавица за преглед и предпазна ръкавица за еднократна употреба

Класификация: Клас I съгл. Регламент за медицинските продукти (EU) 2017/745
Категория III съгл. Регламент за ЛПС (EU) 2016/425

Базовият UDI-DI: 9001570NOT-063GB-N-3DY

semperguard Xpert

Размери	X-Small	Small	Medium	Large	X-Large	XX-Large
Номера на артикулите	-	3000016078	3000016079	3000016080	3000016081	3000016082

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 (2023), ASTM D6319-19 (2023) or ASTM D5250-19 (2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A2:2024, EN 455-2:2024, EN 455-3:2023, 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 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

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 № 2777/11462-04/E01-01 издадено чрез:

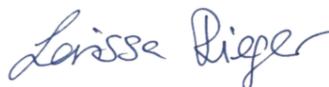
SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

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



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Издадено на: 2025-10-29

Важи до: 2027-10-28

Версия: 003

AB UYGUNLUK BEYANI

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

Üretici

HARPS Investment Asia Pte. Ltd.
#08-10A Marina One West Tower,
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AB'de yetkili temsilci

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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 Yönetmelik uyarınca Sınıf I
KKE Yönetmeliği (AB) 2016/425 uyarınca Kategori III

Temel UDI-DI: 9001570NOT-063GB-N-3DY

semperguard Xpert

Boyutlar	X-Small	Small	Medium	Large	X-Large	XX-Large
Ürün numaraları	-	3000016078	3000016079	3000016080	3000016081	3000016082

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 (2023), ASTM D6319-19 (2023) or ASTM D5250-19 (2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A2:2024, EN 455-2:2024, EN 455-3:2023, 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 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

Yukarıda açıklanan CE işaretli ürünün, (AB) 2016/425 sayılı Kişisel Koruyucu Ekipman Yönetmeliğinin belirleyici hükümlerine uygun olduğunu ve AB Tipi Muayene Sertifika Numarasına tabi olduğunu beyan ederiz. 2777/11462-04/E01-01 verilmiş :

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

Ürünler, aşağıdakilerin gözetimi altında 2016/425 sayılı Yönetmeliğin (AB) Ek VII'sinde (Modül C2) belirtilen prosedüre tabidir

SATRA Technology Europe Ltd, ID No. 2777
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



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Veriliş tarihi: 2025-10-29

Son geçerlilik tarihi: 2027-10-28

Sürüm: 003