EU DECLARATION OF CONFORMITY

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

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

Authorized representative in the EU
HARPS Europe GmbH
Wiedner Guertel 9-13
1100 Vienna, 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: 9001570NOF-032RB-N-32K

sempermed skySense

Lot.# BS20100-BS25100

Sizes	X-Small	Small	Medium	Large	X-Large
Article codes	3000015792	3000015793	3000015794	3000015795	3000015796

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+A1:2022, EN 455-2:2015, 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. 2777/21028-03/E31-01 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 D) 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

Andreas Wöss
Sr Vice President Sales

Released by: Christian Rohrbach
Head of Business Strategy

Issued : 2024-05-06 **Expires:** 2026-05-05 **Version:** 001

EU-KONFORMITÄTSERKLÄRUNG

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

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

EU-Bevollmächtigter
HARPS Europe GmbH
Wiedner Guertel 9-13
1100 Vienna, Austria
sempermed@harpsglobal.com
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

Basic UDI-DI: 9001570NOF-032RB-N-32K

sempermed skySense

Lot.# BS20100-BS25100

Größen	X-Small	Small	Medium	Large	X-Large
Artikelnummern	3000015792	3000015793	3000015794	3000015795	3000015796

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+A1:2022, EN 455-2:2015, 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

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. 2777/21028-03/E31-01 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 D) 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

Andreas Wöss
Sr Vice President Sales

Released by: Christian Rohrbach
Head of Business Strategy

Ausgestellt am: 2024-05-06 **Gültig bis:** 2026-05-05 **Version:** 001

DÉCLARATION UE DE CONFORMITÉ

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

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

Représentant UE
HARPS Europe GmbH
Wiedner Guertel 9-13
1100 Vienna, Austria
sempermed@harpsglobal.com
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 la règlement pour dispositifs médicaux (UE) 2017/745
Catégorie III selon la règlement EPI (UE) 2016/425

Basic UDI-DI: 9001570NOF-032RB-N-32K

sempermed skySense

Lot.# BS20100-BS25100

Tailles	X-Small	Small	Medium	Large	X-Large
Numéros d'article	3000015792	3000015793	3000015794	3000015795	3000015796

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

La déclaration se fonde sur l'annexe IV. Classification selon la règle 5, annexe VIII. Évaluation de la conformité selon l'annexe II.
Normes appliquées : ASTM D3578-19 (2023), ASTM D6319-19 (2023) or ASTM D5250-19 (2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A1:2022, EN 455-2:2015, 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

Par la présente, nous déclarons sous notre propre responsabilité que les produits portant le symbole CE mentionnés ci-dessus sont conformes aux dispositions essentielles de la règlement (UE) 2016/425 concernant l'équipement de protection individuelle sont identiques à l'équipement de protection individuelle faisant l'objet du certificat d'examen de type UE numéro 2777/21028-03/E31-01 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 D) de la règlement (UE) 2016/425 sous la surveillance de

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

Normes appliquées : EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN ISO 374-4:2019, EN ISO 374-5:2016, ISO 2859-1:1999 AMD 1:2011

Andreas Wöss
Sr Vice President Sales

Released by: Christian Rohrbach
Head of Business Strategy

Délivré le : 2024-05-06 **Valable jusqu'au :** 2026-05-05 **Version:** 001

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

Rappresentante autorizzato nell'UE
HARPS Europe GmbH
Wiedner Guertel 9-13
1100 Vienna, Austria
sempermed@harpsglobal.com
SRN: AT-AR-000040870

Questo certificato è valido per il seguente prodotto:

Guanto protettivo non sterile monouso da esame
Clasificazione: Classe I secondo il regolamento dispositivi medici (UE) 2017/745
Categoria III secondo il regolamento (UE) 2016/425 del PPE

Basic UDI-DI: 9001570NOF-032RB-N-32K

sempermed skySense

Lot.# BS20100-BS25100

Misure	X-Small	Small	Medium	Large	X-Large
Codici articolo	3000015792	3000015793	3000015794	3000015795	3000015796

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

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+A1:2022, EN 455-2:2015, 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. 2777/21028-03/E31-01 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 D) 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

Andreas Wöss
Sr Vice President Sales

Released by: Christian Rohrbach
Head of Business Strategy

Rilasciato : 2024-05-06 **Scade:** 2026-05-05 **Version:** 001

EU-CONFORMITEITSVERKLARING

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

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

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

Dit certificaat is geldig voor de volgende producten:

Niet-steriele onderzoeks- en beschermende handschoenen voor eenmalig gebruik
Classificatie: Klasse I volgens Verordening (EU) 2017/745 betreffende medische hulpmiddelen
Categorie III volgens PBM-verordening (EU) 2016/425

Basic UDI-DI: 9001570NOF-032RB-N-32K

sempermed skySense

Lot.# BS20100-BS25100

Maten	X-Small	Small	Medium	Large	X-Large
Artikelnummers	3000015792	3000015793	3000015794	3000015795	3000015796

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

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+A1:2022, EN 455-2:2015, 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

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.2777/21028-03/E31-01 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 D) 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

Andreas Wöss
Sr Vice President Sales

Released by: Christian Rohrbach
Head of Business Strategy

Geldig tot: 2024-05-06 **Geldig tot:** 2026-05-05 **Version:** 001

DECLARACIÓN UE DE CONFORMIDAD

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

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

Representante de la UE
HARPS Europe GmbH
Wiedner Guertel 9-13
1100 Vienna, Austria
sempermed@harpsglobal.com
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

Basic UDI-DI: 9001570NOF-032RB-N-32K

sempermed skySense

Lot.# BS20100-BS25100

Tamaños	X-Small	Small	Medium	Large	X-Large
Número de artículo	3000015792	3000015793	3000015794	3000015795	3000015796

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

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+A1:2022, EN 455-2:2015, 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

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. 2777/21028-03/E31-01 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 D) 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

Andreas Wöss
Sr Vice President Sales

Released by: Christian Rohrbach
Head of Business Strategy

Expedido el: 2024-05-06 **Válido hasta:** 2026-05-05 **Version:** 001

DECLARAÇÃO DE CONFORMIDADE UE

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

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

Representante da UE
HARPS Europe GmbH
Wiedner Guertel 9-13
1100 Vienna, Austria
sempermed@harpsglobal.com
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

Basic UDI-DI: 9001570NOF-032RB-N-32K

sempermed skySense

Lot.# BS20100-BS25100

Tamanhos	X-Small	Small	Medium	Large	X-Large
Números de artigo	3000015792	3000015793	3000015794	3000015795	3000015796

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

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

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+A1:2022, EN 455-2:2015, 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 2777/21028-03/E31-01 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 D) 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

Andreas Wöss
Sr Vice President Sales

Released by: Christian Rohrbach
Head of Business Strategy

Emitido em: 2024-05-06 **Válido até:** 2026-05-05 **Version:** 001

EU-FÖRSÄKRAN OM ÖVERENSSTÄMMELSE

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

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

Behörig representant hos EU
HARPS Europe GmbH
Wiedner Guertel 9-13
1100 Vienna, 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

Basic UDI-DI: 9001570NOF-032RB-N-32K

sempermed skySense

Lot.# BS20100-BS25100

Storlekar	X-Small	Small	Medium	Large	X-Large
Artikelkoder	3000015792	3000015793	3000015794	3000015795	3000015796

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

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

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+A1:2022, EN 455-2:2015, 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

Vi förklarar härmed under eget exklusivt ansvar att ovan beskrivna, CE-markerade produkt stämmer överens med tillämpliga bestämmelser i EU-förordningen 2016/425 för personlig skyddsutrustning och är identisk med den personliga skyddsutrustning som anges i EU-certifikat för typgranskning nummer2777/21028-03/E31-01 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 D) till EU-förordningen 2016/425 under the supervision of under uppsikt av
SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Tillämpade standarder: EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN ISO 374-4:2019, EN ISO 374-5:2016, ISO 2859-1:1999 AMD 1:2011

Andreas Wöss
Sr Vice President Sales

Released by: Christian Rohrbach
Head of Business Strategy

Daterad : 2024-05-06 **Giltig till:** 2026-05-05 **Version:** 001

EU-OVERENSSTEMMELSESERKLÆRING

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

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

EU-befuldmægtigede
HARPS Europe GmbH
Wiedner Guertel 9-13
1100 Vienna, 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

Basic UDI-DI: 9001570NOF-032RB-N-32K

sempermed skySense

Lot.# BS20100-BS25100

Størrelser	**X-Small**	**Small**	**Medium**	**Large**	**X-Large**
Artikelnumre	3000015792	3000015793	3000015794	3000015795	3000015796

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

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

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+A1:2022, EN 455-2:2015, 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

Vi bekræfter hermed under fuldt ansvar, at de ovenfor nævnte CE-mærkede produkter stemmer overens med med de afgørende bestemmelser i forordningen (EU) 2016/425 for personlige værnemidler, og er genstand for EU-certificering af typeafprøvning nr.2777/21028-03/E31-01 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 D) 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

Andreas Wöss
Sr Vice President Sales

Released by: Christian Rohrbach
Head of Business Strategy

Udstedt den: 2024-05-06 **Gyldig til:** 2026-05-05 **Version:** 001

EU KONFORMITETSERKLÆRING

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

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

Autorisert representant i EU
HARPS Europe GmbH
Wiedner Guertel 9-13
1100 Vienna, Austria
sempermed@harpsglobal.com
SRN: AT-AR-000040870

Dette sertifikatet er gyldig for følgende produkter:

Ikke-steril undersøkelses- og beskyttelseshanske for engangsbruk

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

Basic UDI-DI: 9001570NOF-032RB-N-32K

sempermed skySense

Lot.# BS20100-BS25100

Størrelser	X-Small	Small	Medium	Large	X-Large
Artikkelnumre	3000015792	3000015793	3000015794	3000015795	3000015796

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

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

Relevante standarder: ASTM D3578-19 (2023), ASTM D6319-19 (2023) or ASTM D5250-19 (2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A1:2022, EN 455-2:2015, 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

Vi erklærer herved under eneansvar at det CE-merkede produktet som er nevnt ovenfor oppfyller de relevante bestemmelsene i Forordning (EU) nr. 2016/425 om personlig verneutstyr og er gjenstand for EU-typeprøvesertifikat nr. 2777/21028-03/E31-01 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 D) i Forordning nr. 2016/425 under tilsyn av

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

Relevante standarder: EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN ISO 374-4:2019, EN ISO 374-5:2016, ISO 2859-1:1999 AMD 1:2011

Andreas Wöss
Sr Vice President Sales

Released by: Christian Rohrbach
Head of Business Strategy

Utstedt den: 2024-05-06 **Gyldig til:** 2026-05-05 **Version:** 001

EU-VAATIMUSTENMUKAISUUSVAKUUTUS

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

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

EU:n valtuutettu edustaja
HARPS Europe GmbH
Wiedner Guertel 9-13
1100 Vienna, Austria
sempermed@harpsglobal.com
SRN: AT-AR-000040870

Tämä sertifikaatti 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

Basic UDI-DI: 9001570NOF-032RB-N-32K

sempermed skySense

Lot.# BS20100-BS25100

Koot	X-Small	Small	Medium	Large	X-Large
Tuotenumerot	3000015792	3000015793	3000015794	3000015795	3000015796

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

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+A1:2022, EN 455-2:2015, 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

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 2777/21028-03/E31-01 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 D) 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

Andreas Wöss
Sr Vice President Sales

Released by: Christian Rohrbach
Head of Business Strategy

Laadittu : 2024-05-06 **Voimassa (asti):** 2026-05-05 **Version:** 001

ES ATITIKTIES DEKLARACIJA

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

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

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

Sis sertifikatas galioja toliau nurodytiems produktams:

Nesterilios vienkartinio naudojimo apžiūros ir apsauginės pirštinės
Klasifikacija: I klasė pagal reglamentą dėl medicinos prietaisų (ES) 2017/745
III kategorija pagal reglamentą (ES) 2016/425 dėl asmeninių apsaugos priemonių

Basic UDI-DI: 9001570NOF-032RB-N-32K

sempermed skySense

Lot.# BS20100-BS25100

Dydžiai	X-Small	Small	Medium	Large	X-Large
Prekių numeriai	3000015792	3000015793	3000015794	3000015795	3000015796

Prisiimdami visą atsakomybę šiuo dokumentu patvirtiname, kad CE paženklinti 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+A1:2022, EN 455-2:2015, 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 paženklinti produktai atitinka svarbiausius reglamentą dėl asmeninių apsaugos priemonių (ES) 2016/425 reikalavimus ir yra ES tipo tyrimo sertifikato Nr. objektas. 2777/21028-03/E31-01 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 D) 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

Andreas Wöss
Sr Vice President Sales

Released by: Christian Rohrbach
Head of Business Strategy

Išduota : 2024-05-06 **Galioja iki:** 2026-05-05 **Version:** 001

ES ATBILSTĪBAS DEKLARĀCIJA

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

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

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

Sis sertifikāts ir derīgs šādam produktam:

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

Basic UDI-DI: 9001570NOF-032RB-N-32K

sempermed skySense

Lot.# BS20100-BS25100

Izmēri	X-Small	Small	Medium	Large	X-Large
Artikula numurs	3000015792	3000015793	3000015794	3000015795	3000015796

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

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+A1:2022, EN 455-2:2015, 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

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. 2777/21028-03/E31-01 izdots :

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

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

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

Piemērotie standarti: EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN ISO 374-4:2019, EN ISO 374-5:2016, ISO 2859-1:1999 AMD 1:2011

Andreas Wöss
Sr Vice President Sales

Released by: Christian Rohrbach
Head of Business Strategy

Izdots : 2024-05-06 **Derīgs līdz:** 2026-05-05 **Version:** 001

ELI VASTAVUSDEKLARATSIOON

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

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

Volitatud esindaja EL-is
HARPS Europe GmbH
Wiedner Guertel 9-13
1100 Vienna, Austria
sempermed@harpsglobal.com
SRN: AT-AR-000040870

See sertifikaat kehtib järgmistele toodetele:

Mittesteriilne läbivaatus- ja kaitsekinnas ühekordseks kasutuseks
Klassifikatsioon: I klass kooskõlas meditsiinitoodete määrusega (EU) 2017/745
III kategooria kooskõlas isikukaitsevahendite määrusega (EL) 2016/425

Basic UDI-DI: 9001570NOF-032RB-N-32K

sempermed skySense

Lot.# BS20100-BS25100

Suurused	X-Small	Small	Medium	Large	X-Large
Tootenumbrid	3000015792	3000015793	3000015794	3000015795	3000015796

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

Deklaratsioon põhineb IV lisal. Klassifikatsioon kooskõlas VIII lisa 5. reegliga. 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+A1:2022, EN 455-2:2015, 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 tooted on kooskõlas isikukaitsevahendite määruse (EL) 2016/425 põhisätetega ning on identsed isikukaitsevahenditega, mille kohta on välja antud EÜ tüübihindamistõend nr2777/21028-03/E31-01 välja :

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

Toodetele kohaldub määruse (EL) 2016/425 VII lisa (moodul D) 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

Andreas Wöss
Sr Vice President Sales

Released by: Christian Rohrbach
Head of Business Strategy

Välja andmise aeg : 2024-05-06 **Kehtivusaeg:** 2026-05-05 **Version:** 001

EU PROHLÁŠENÍ O SHODĚ

NARIZENI O ZDRAVOTNICKYCH PROSTREDCICH (EU) 2017/745
NARIZENI (EU) 2016/425 PRO OSOBNI OCHRANNE PROSTREDKY

Výrobce

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

EU zplnomocněný zástupce

HARPS Europe GmbH
Wiedner Guertel 9-13
1100 Vienna, 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

Basic UDI-DI: 9001570NOF-032RB-N-32K

sempermed skySense

Lot.# BS20100-BS25100

Velikosti	X-Small	Small	Medium	Large	X-Large
Číslo produktu	3000015792	3000015793	3000015794	3000015795	3000015796

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

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

Použité normy: ASTM D3578-19 (2023), ASTM D6319-19 (2023) or ASTM D5250-19 (2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A1:2022, EN 455-2:2015, 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.2777/21028-03/E31-01 vystaveno :

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

Produkty jsou předmětem procesu podle dodatku VII (moduly, D) 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

Andreas Wöss
Sr Vice President Sales

Released by: Christian Rohrbach
Head of Business Strategy

Vystaveno dne: 2024-05-06 **Platné do:** 2026-05-05 **Version:** 001

EÚ VYHLÁSENIE O ZHODE

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

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

Splnomocnenec pre EU
HARPS Europe GmbH
Wiedner Guertel 9-13
1100 Vienna, 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 (EU) 2017/745 o zdravotníckych pomôckach
Kategória III podľa Nariadenia o osobných ochranných pomôckach (EU) 2016/425

Basic UDI-DI: 9001570NOF-032RB-N-32K

sempermed skySense

Veľkosti	**X-Small**	**Small**	**Medium**	**Large**	**X-Large**
Výrobné čísla	3000015792	3000015793	3000015794	3000015795	3000015796

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

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

Súvisiace normy: ASTM D3578-19 (2023), ASTM D6319-19 (2023) or ASTM D5250-19 (2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A1:2022, EN 455-2:2015, 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 EU - Osvedčenia o typovej skúške č. 2777/21028-03/E31-01 vyhotovené :

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

Výrobky sú predmetom konania podľa dodatku VII (moduly D) 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

Andreas Wöss
Sr Vice President Sales

Released by: Christian Rohrbach
Head of Business Strategy

Vyhotovené dňa: 2024-05-06 **Platné do:** 2026-05-05 **Version:** 001

EU-MEGFELELŐSÉGI NYILATKOZAT

ORVOSTECHNIKAI ESZKOZOKRÖL SZÓLÓ (EU) 2017/745 RENDELET
EGYÉNI VÉDŐESZKOZOKRÖL SZÓLÓ (EU) 2016/425 RENDELET

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

EU-meghatalmazott
HARPS Europe GmbH
Wiedner Guertel 9-13
1100 Vienna, 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

Basic UDI-DI: 9001570NOF-032RB-N-32K

sempermed skySense

Lot.# BS20100-BS25100

Méretek	**X-Small**	**Small**	**Medium**	**Large**	**X-Large**
Cikkszámok	3000015792	3000015793	3000015794	3000015795	3000015796

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

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

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+A1:2022, EN 455-2:2015, 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,

Ezennel kizárólagos felelősségünk mellett kijelentjük, hogy a fent említett CE jelzésű termékek megfelelnek az egyéni védőeszközökre irányuló 2016/425/EU rendelet vonatkozó előírásainak és vonatkozik rájuk a megfelelő számú EU-típusvizsgálati tanúsítvány 2777/21028-03/E31-01 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 (D 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

Andreas Wöss
Sr Vice President Sales

Released by: Christian Rohrbach
Head of Business Strategy

Kelt : 2024-05-06 **Érvényes:** 2026-05-05 **Version:** 001

IZJAVA EU O SKLADNOSTI

UREDBA O MEDICINSKIH PRIPOMOČKIH (EU) 2017/745/EGS

UREDBA (EU) 2016/425 ZA OSEBNO VAROVALNO OPREMO

Proizvajalec

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

Pooblaščen zastopnik EU

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

To potrdilo velja za naslednje izdelke:

Nesterilne zaščitne rokavice in rokavice za preglede za enkratno uporabo

Klasifikacija: Razred I v skladu z Uredbo o medicinskih pripomočkih (EU) 2017/745/EGS

Kategorija III v skladu z Uredbo OVO (EU) 2016/425

Basic UDI-DI: 9001570NOF-032RB-N-32K

sempermed skySense

Lot.# BS20100-BS25100

Velikosti	**X-Small**	**Small**	**Medium**	**Large**	**X-Large**
Stevilke izdelkov	3000015792	3000015793	3000015794	3000015795	3000015796

S to izključno odgovornostjo izjavljamo, da so izdelki z oznako CE v skladu z zahtevami Uredbe za medicinske pripomočke (EU) 2017/745.

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

Uporabljeni standardi: ASTM D3578-19 (2023), ASTM D6319-19 (2023) or ASTM D5250-19 (2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A1:2022, EN 455-2:2015, 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

S to izključno odgovornostjo izjavljamo, da so zgoraj navedeni izdelki z oznako CE v skladu z bistvenimi zahtevami Uredbe (EU) 2016/425 za osebno varovalno opremo in so predmet certifikata ES o pregledu tipa št. 2777/21028-03/E31-01 izdano :

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

Izdelki so predmet postopka v skladu s Prilogo VII (modul D) 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

Andreas Wöss
Sr Vice President Sales

Released by: Christian Rohrbach
Head of Business Strategy

Izdano dne: 2024-05-06 **Veljavno do:** 2026-05-05 **Version:** 001

EU IZJAVA O SUKLADNOSTI

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

Proizvođač

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

Ovlašteni predstavnik u EU

HARPS Europe GmbH
Wiedner Guertel 9-13
1100 Vienna, 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

Basic UDI-DI: 9001570NOF-032RB-N-32K

sempermed skySense

Lot.# BS20100-BS25100

Veličine	X-Small	Small	Medium	Large	X-Large
Br. artikla	3000015792	3000015793	3000015794	3000015795	3000015796

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+A1:2022, EN 455-2:2015, 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

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.2777/21028-03/E31-01 izdano :

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

Proizvodi podliježu postupku iz Dodatka VII. (modul D) 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

Andreas Wöss
Sr Vice President Sales

Released by: Christian Rohrbach
Head of Business Strategy

Izdano dana: 2024-05-06 **Vrijedi do:** 2026-05-05 **Version:** 001

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

Autoryzowany przedstawiciel w UE
HARPS Europe GmbH
Wiedner Guertel 9-13
1100 Vienna, 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: 9001570NOF-032RB-N-32K

sempermed skySense

Lot.# BS20100-BS25100

Rozmiary	X-Small	Small	Medium	Large	X-Large
Numery artykułów	3000015792	3000015793	3000015794	3000015795	3000015796

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

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+A1:2022, EN 455-2:2015, 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 2777/21028-03/E31-01 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 D) 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

Andreas Wöss
Sr Vice President Sales

Released by: Christian Rohrbach
Head of Business Strategy

Data wydania: 2024-05-06 **Data ważności:** 2026-05-05 **Version:** 001

DECLARAȚIA DE CONFORMITATE UE

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

Producător

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

Persoană împuternicită EU

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

Acest certificat este valabil pentru următoarele produse:

Mânușă de consult și de protecție nesterilă de unică folosință

clasificare: Clasa I conform règlementi privind produsele medicale (EU) 2017/745
Categoria III conform ordonanței EPP (EU) 2016/425

Basic UDI-DI: 9001570NOF-032RB-N-32K

sempermed skySense

Lot.# BS20100-BS25100

mărimi	**X-Small**	**Small**	**Medium**	**Large**	**X-Large**
Numerele de articole	3000015792	3000015793	3000015794	3000015795	3000015796

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

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

Normele aplicate: ASTM D3578-19 (2023), ASTM D6319-19 (2023) or ASTM D5250-19 (2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A1:2022, EN 455-2:2015, 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 confirmăm preluând toată responsabilitatea că produsele marcate CE indicate mai sus corespund cerințelor de bază (EU) 2016/425 pentru echipamente personale de protecție și acestea sunt obiectul certificării de tip CE nr. 2777/21028-03/E31-01 eliberat prin:

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

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

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

Normele aplicate: EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN ISO 374-4:2019, EN ISO 374-5:2016, ISO 2859-1:1999 AMD 1:2011

Andreas Wöss
Sr Vice President Sales

Released by: Christian Rohrbach
Head of Business Strategy

Eliberat la data de: 2024-05-06 **Valabil până în:** 2026-05-05 **Version:** 001

ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ ΕΕ

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

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

Εξουσιοδοτημένος αντιπρόσωπος στην ΕΕ
HARPS Europe GmbH
Wiedner Guertel 9-13
1100 Vienna, 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 (EU) 2017/745 περί ιατροτεχνολογικών προϊόντων
Κατηγορία II σύμφωνα με τον Κανονισμό (ΕΕ) 2016/425 περί ΜΑΠ

Basic UDI-DI: 9001570NOF-032RB-N-32K

sempermed skySense

Μεγέθη	X-Small	Small	Medium	Large	X-Large
Αριθμοί προϊόντος	3000015792	3000015793	3000015794	3000015795	3000015796

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

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

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+A1:2022, EN 455-2:2015, 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,

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. 2777/21028-03/E31-01 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 D) 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

Andreas Wöss
Sr Vice President Sales

Released by: Christian Rohrbach
Head of Business Strategy

Εκδόθηκε : 2024-05-06 **Ισχύει έως:** 2026-05-05 **Version:** 001

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

Упълномощен представител в ЕС
HARPS Europe GmbH
Wiedner Guertel 9-13
1100 Vienna, Austria
sempermed@harpsglobal.com
SRN: AT-AR-000040870

Настоящият сертификат важи за следните продукти:

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

Basic UDI-DI: 9001570NOF-032RB-N-32K

sempermed skySense

Lot.# BS20100-BS25100

Размери	X-Small	Small	Medium	Large	X-Large
Номера на артикулите	3000015792	3000015793	3000015794	3000015795	3000015796

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

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+A1:2022, EN 455-2:2015, 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 Nr. 2777/21028-03/E31-01 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

Andreas Wöss
Sr Vice President Sales

Released by: Christian Rohrbach
Head of Business Strategy

Издадено на: 2024-05-06 **Важи до:** 2026-05-05 **Version:** 001

UYGUNLUK BEYANI

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

Uretici

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

AB'de yetkili temsilci

HARPS Europe GmbH
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SRN: AT-AR-000040870

Bu sertifika aşağıdaki ürün için geçerlidir:

Tek kullanımlık steril olmayan muayene ve koruyucu eldiven
Sınıflandırma: Tıbbi cihazlarla ilgili 2017/745 (AB) sayılı Tüzük uyarınca Sınıf I
KKE Yönetmeliği (AB) 2016/425 uyarınca Kategori III

Basic UDI-DI: 9001570NOF-032RB-N-32K

sempermed skySense

Lot.# BS20100-BS25100

Boyutlar	X-Small	Small	Medium	Large	X-Large
Ürün numaraları	3000015792	3000015793	3000015794	3000015795	3000015796

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

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+A1:2022, EN 455-2:2015, 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

Yukarıda açıklanan CE işaretli ürünün, (AB) 2016/425 sayılı Kişisel Koruyucu Ekipman Tüzüğünün belirleyici hükümlerine uygun olduğunu ve AB Tipi Muayene Sertifika Numarasına tabi olduğunu beyan ederiz. 2777/21028-03/E31-01 veriliş :

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

Ürünler, aşağıdakilerin gözetimi altında 2016/425 sayılı Tüzüğün (AB) Ek VII'sinde (Modül D) 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

Andreas Wöss
Sr Vice President Sales

Released by: Christian Rohrbach
Head of Business Strategy

Veriliş tarihi: 2024-05-06 **Son geçerlilik tarihi:** 2026-05-05 **Version:** 001