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:

Sterile examination and protective glove for single use
Classification: Class Is according to MD Regulation (EU) 2017/745
Category III according to PPE Regulation (EU) 2016/425

Basic UDI-DI: 9001570N*F-047OB-S-3TK

sempermed safe sterile

Sizes	X-Small	Small	Medium	Large	X-Large	XX-Large
Article codes		3000016225	3000016226	3000016227	3000016228	

We hereby declare under sole responsibility that the CE 0123 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 IX.

Applied standards: ASTM D3577-19(2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A1:2022, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009, EN 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015/A1:2023, EN ISO 11607-1:2020/A11:2022, EN ISO 11607-2:2020/A11:2022, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EU Certificate No.: G11 088308 0023 Rev. 01

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. 2777/11461-05/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: 2025-06-24 **Expires:** 2027-06-23 **Version:** 001

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,
9 Straits View, Singapore 018937, Singapore
sempermed@harpsglobal.com
SRN: SG-MF-000001645

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

Dieses Zertifikat ist gültig für die folgenden Produkte:

Steriler Untersuchungs- und Schutzhandschuh für den Einmalgebrauch
Klassifizierung: Klasse Is gemäß Medizinprodukteverordnung (EU) 2017/745
Kategorie III gemäß PSA Verordnung (EU) 2016/425

Basis-UDI-DI: 9001570N*F-047OB-S-3TK

sempermed safe sterile

Größen	X-Small	Small	Medium	Large	X-Large	XX-Large
Artikelnummern		3000016225	3000016226	3000016227	3000016228	

Wir bestätigen hiermit unter alleiniger Verantwortung, dass die CE 0123 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 IX.

Angewandte Normen: ASTM D3577-19(2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A1:2022, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009, EN 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015/A1:2023, EN ISO 11607-1:2020/A11:2022, EN ISO 11607-2:2020/A11:2022, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EU Certificate No.: G11 088308 0023 Rev. 01

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. 2777/11461-05/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: 2025-06-24 **Gültig bis:** 2027-06-23 **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.
#08-10A Marina One West Tower,
9 Straits View, Singapore 018937, Singapore
sempermed@harpsglobal.com
SRN: SG-MF-000001645

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

Ce certificat est valable pour les produits suivants :

Gant d'examen et de protection stérile à usage unique
Classification : Classe Is selon le règlement pour dispositifs médicaux (UE) 2017/745
Catégorie III selon le règlement EPI (UE) 2016/425

IUD-ID de base: 9001570N*F-047OB-S-3TK

sempermed safe sterile

Tailles	X-Small	Small	Medium	Large	X-Large	XX-Large
Numéros d'article		3000016225	3000016226	3000016227	3000016228	

Par la présente, nous déclarons sous notre propre responsabilité que les produits portant le symbole CE 0123 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 IX.

Normes appliquées : ASTM D3577-19(2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A1:2022, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009, EN 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015/A1:2023, EN ISO 11607-1:2020/A11:2022, EN ISO 11607-2:2020/A11:2022, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EU Certificate No.: G11 088308 0023 Rev. 01

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 2777/11461-05/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 : 2025-06-24 **Valable jusqu'au :** 2027-06-23 **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.
#08-10A Marina One West Tower,
9 Straits View, Singapore 018937, Singapore
sempermed@harpsglobal.com
SRN: SG-MF-000001645

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

Questo certificato è valido per il seguente prodotto:

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

UDI-DI di base: 9001570N*F-047OB-S-3TK

sempermed safe sterile

Misure	X-Small	Small	Medium	Large	X-Large	XX-Large
Codici articolo		3000016225	3000016226	3000016227	3000016228	

Con la presente, dichiariamo sotto la nostra esclusiva responsabilità che il prodotto con marchio CE 0123 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 IX.

Norme applicate: ASTM D3577-19(2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A1:2022, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009, EN 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015/A1:2023, EN ISO 11607-1:2020/A11:2022, EN ISO 11607-2:2020/A11:2022, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EU Certificate No.: G11 088308 0023 Rev. 01

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. 2777/11461-05/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 : 2025-06-24 **Scade:** 2027-06-23 **Version:** 001

EU-CONFORMITEITSVERKLARING

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

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

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

Dit certificaat is geldig voor de volgende producten:

Steriele onderzoeks- en beschermende handschoenen voor eenmalig gebruik
Classificatie: De klasse Is volgens Verordening (EU) 2017/745 betreffende medische hulpmiddelen
Categorie III volgens PBM-verordening (EU) 2016/425

Basic UDI-DI: 9001570N*F-047OB-S-3TK

sempermed safe sterile

Maten	X-Small	Small	Medium	Large	X-Large	XX-Large
Artikelnummers		3000016225	3000016226	3000016227	3000016228	

Wij verklaren hierbij onder uitsluitende verantwoordelijkheid, dat de CE 0123-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 IX.

Toegepaste normen: ASTM D3577-19(2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A1:2022, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009, EN 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015/A1:2023, EN ISO 11607-1:2020/A11:2022, EN ISO 11607-2:2020/A11:2022, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EU Certificate No.: G11 088308 0023 Rev. 01

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.2777/11461-05/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: 2025-06-24 **Geldig tot:** 2027-06-23 **Versie:** 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.
#08-10A Marina One West Tower,
9 Straits View, Singapore 018937, Singapore
sempermed@harpsglobal.com
SRN: SG-MF-000001645

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

El presente certificado es válido para los siguientes productos:

Guante estéril de exploración y protección para un solo uso
Clasificación: Clase Is según el Reglamento de Productos Medicinales (EU) 2017/745
Categoría III según el Reglamento EPI (UE) 2016/425

UDI-DI básico: 9001570N*F-047OB-S-3TK

sempermed safe sterile

Tamaños	X-Small	Small	Medium	Large	X-Large	XX-Large
Número de artículo		3000016225	3000016226	3000016227	3000016228	

Por la presente confirmamos bajo nuestra exclusiva responsabilidad que los productos con marcado CE 0123 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 IX.

Normas aplicadas: ASTM D3577-19(2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A1:2022, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009, EN 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015/A1:2023, EN ISO 11607-1:2020/A11:2022, EN ISO 11607-2:2020/A11:2022, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EU Certificate No.: G11 088308 0023 Rev. 01

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. 2777/11461-05/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: 2025-06-24 **Válido hasta:** 2027-06-23 **Versión:** 001

DECLARAÇÃO DE CONFORMIDADE UE

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

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

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

Este certificado é válido para os seguintes produtos:

Luva de exame e de proteção estéril para uso único
Classificação: Classe Is 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: 9001570N*F-047OB-S-3TK

sempermed safe sterile

Tamanhos	X-Small	Small	Medium	Large	X-Large	XX-Large
Números de artigo		3000016225	3000016226	3000016227	3000016228	

Declaramos desta forma, sob a nossa exclusiva responsabilidade, que os produtos com a marca CE 0123 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 IX.

Normas aplicadas: ASTM D3577-19(2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A1:2022, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009, EN 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015/A1:2023, EN ISO 11607-1:2020/A11:2022, EN ISO 11607-2:2020/A11:2022, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EU Certificate No.: G11 088308 0023 Rev. 01

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 2777/11461-05/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: 2025-06-24 **Válido até:** 2027-06-23 **Versão:** 001

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,
9 Straits View, Singapore 018937, Singapore
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:

Steril inspektions- och skyddshandske för engångsanvändning
Klassificering: Klass Is 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: 9001570N*F-047OB-S-3TK

sempermed safe sterile

Storlekar	X-Small	Small	Medium	Large	X-Large	XX-Large
Artikelnummer		3000016225	3000016226	3000016227	3000016228	

Vi förklarar härmed under eget exklusivt ansvar att ovan beskrivna, CE 0123-markerade produkt stämmer överens med kraven i EU-förordningen för medicintekniska produkter (EU) 2017/745.

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

Tillämpade standarder: ASTM D3577-19(2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A1:2022, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009, EN 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015/A1:2023, EN ISO 11607-1:2020/A11:2022, EN ISO 11607-2:2020/A11:2022, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EU Certificate No.: G11 088308 0023 Rev. 01

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 nummer2777/11461-05/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 : 2025-06-24 **Giltig till:** 2027-06-23 **Version:** 001

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:

Steril undersøgelseshandske til engangsbrug
Klassificering: Klasse Is jævnfør (EU) 2017/745 -forordningen for medicinsk udstyr
Kategori III jævnfør PVM-forordningen (EU) 2016/425

Grundlæggende UDI-DI: 9001570N*F-047OB-S-3TK

sempermed safe sterile

Størrelser	X-Small	Small	Medium	Large	X-Large	XX-Large
Artikelnumre		3000016225	3000016226	3000016227	3000016228	

Vi bekræfter hermed under fuldt ansvar, at de ovenfor nævnte CE 0123-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 IX.

Anvendte standarder: ASTM D3577-19(2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A1:2022, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009, EN 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015/A1:2023, EN ISO 11607-1:2020/A11:2022, EN ISO 11607-2:2020/A11:2022, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EU Certificate No.: G11 088308 0023 Rev. 01

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.2777/11461-05/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: 2025-06-24 **Gyldig til:** 2027-06-23 **Version:** 001

EU-SAMSVARSERKLÆRING

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:

Steril undersøkelses- og beskyttelseshanske for engangsbruk
Klassifisering: Klasse Is i henhold til EU-forordning om medisinsk utstyr 2017/745
Kategori III i henhold til PVU-forordningen (EU) nr. 2016/425

Basic UDI-DI: 9001570N*F-047OB-S-3TK

sempermed safe sterile

Størrelser	X-Small	Small	Medium	Large	X-Large	XX-Large
Artikkelnumre		3000016225	3000016226	3000016227	3000016228	

Vi erklærer herved under eneansvar at det CE 0123-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 IX.

Anvendte standarder: ASTM D3577-19(2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A1:2022, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009, EN 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015/A1:2023, EN ISO 11607-1:2020/A11:2022, EN ISO 11607-2:2020/A11:2022, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EU Certificate No.: G11 088308 0023 Rev. 01

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. 2777/11461-05/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: 2025-06-24 **Utløper:** 2027-06-23 **Versjon:** 001

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 sertifikaatti koskee seuraavia tuotteita:

Kertakäyttöinen steriili tutkimus- ja suojakäsine
Luokitus: Luokka Is lääkinnällisiä laitteita koskevan asetuksen (EU) 2017/745 mukaisesti
Luokka III henkilönsuojaimista annetun asetuksen (EU) 2016/425 mukaisesti

Yksilöllisen UDI-DI: 9001570N*F-047OB-S-3TK

sempermed safe sterile

Koot	X-Small	Small	Medium	Large	X-Large	XX-Large
Tuotenumerot		3000016225	3000016226	3000016227	3000016228	

Täten vahvistamme yksinomaisella vastuullamme, että CE 0123-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 IX.

Sovelletut standardit: ASTM D3577-19(2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A1:2022, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009, EN 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015/A1:2023, EN ISO 11607-1:2020/A11:2022, EN ISO 11607-2:2020/A11:2022, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EU Certificate No.: G11 088308 0023 Rev. 01

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 2777/11461-05/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 : 2025-06-24 **Voimassa (asti):** 2027-06-23 **Versio:** 001

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:

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

Bazinis UDI-DI: 9001570N*F-047OB-S-3TK

sempermed safe sterile

Dydžiai	X-Small	Small	Medium	Large	X-Large	XX-Large
Prekių numeriai		3000016225	3000016226	3000016227	3000016228	

Prisiimdami visą atsakomybę šiuo dokumentu patvirtiname, kad CE 0123 paženklinti produktai atitinka reglamentą dėl medicinos prietaisų (ES) 2017/745 reikalavimus.

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

Taikomi standartai: ASTM D3577-19(2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A1:2022, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009, EN 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015/A1:2023, EN ISO 11607-1:2020/A11:2022, EN ISO 11607-2:2020/A11:2022, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EU Certificate No.: G11 088308 0023 Rev. 01

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. 2777/11461-05/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 : 2025-06-24 **Galioja iki:** 2027-06-23 **Versija:** 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.
#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:

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

Pamata UDI-DI: 9001570N*F-047OB-S-3TK

sempermed safe sterile

Izmēri	X-Small	Small	Medium	Large	X-Large	XX-Large
Artikula numurs		3000016225	3000016226	3000016227	3000016228	

Ar šo mēs apliecinām, ka iepriekš aprakstītais produkts ar CE 0123 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 IX pielikums.

Piemērotie standarti: ASTM D3577-19(2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A1:2022, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009, EN 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015/A1:2023, EN ISO 11607-1:2020/A11:2022, EN ISO 11607-2:2020/A11:2022, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EU Certificate No.: G11 088308 0023 Rev. 01

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. 2777/11461-05/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 : 2025-06-24 **Derīgs līdz:** 2027-06-23 **Versija:** 001

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:

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

Põhi-UDI-DI: 9001570N*F-047OB-S-3TK

sempermed safe sterile

Suurused	X-Small	Small	Medium	Large	X-Large	XX-Large
Tootenumbrid		3000016225	3000016226	3000016227	3000016228	

Kinnitame oma ainuvastutusel, et CE 0123-märgisega tooted on kooskõlas meditsiinitoodete määruse (EU) 2017/745 nõuetega.

Deklaratsioon põhineb IV lisal. Klassifikatsioon kooskõlas VIII lisa 5. reegliga. Vastavushindamine põhineb IX lisal.

Kohaldatud normid: ASTM D3577-19(2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A1:2022, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009, EN 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015/A1:2023, EN ISO 11607-1:2020/A11:2022, EN ISO 11607-2:2020/A11:2022, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EU Certificate No.: G11 088308 0023 Rev. 01

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 nr2777/11461-05/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 : 2025-06-24 **Aegub:** 2027-06-23 **Versioon:** 001

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:

Sterilní vyšetřovací a ochranné rukavice pro jednorázové použití
Klasifikace Třída Is podle nařízení o zdravotnických prostředcích (EU) 2017/745
Kategorie III podle nařízení o OOP (EU) 2016/425

Základní UDI-DI: 9001570N*F-047OB-S-3TK

sempermed safe sterile

Velikosti	X-Small	Small	Medium	Large	X-Large	XX-Large
Číslo produktu		3000016225	3000016226	3000016227	3000016228	

Tímto potvrzujeme s výlučnou odpovědností, že produkty označené CE 0123 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 IX.

Použité normy: ASTM D3577-19(2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A1:2022, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009, EN 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015/A1:2023, EN ISO 11607-1:2020/A11:2022, EN ISO 11607-2:2020/A11:2022, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EU Certificate No.: G11 088308 0023 Rev. 01

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.2777/11461-05/E01-01vystaveno:

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: 2025-06-24 **Platné do:** 2027-06-23 **Verze:** 001

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:

Sterilné vyšetrovacie a ochranné rukavice na jedno použitie
Klasifikácia: Trieda Is podľa Nariadenia (EÚ) 2017/745 o zdravotníckych pomôckach
Kategória III podľa Nariadenia o osobných ochranných pomôckach (EÚ) 2016/425

Základný UDI-DI 9001570N*F-047OB-S-3TK

sempermed safe sterile

Veľkosti	X-Small	Small	Medium	Large	X-Large	XX-Large
Výrobné čísla		3000016225	3000016226	3000016227	3000016228	

Týmto vo svojej výhradnej zodpovednosti potvrdzujeme, že výrobky označené symbolom CE 0123 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 IX.

Súvisiace normy: ASTM D3577-19(2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A1:2022, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009, EN 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015/A1:2023, EN ISO 11607-1:2020/A11:2022, EN ISO 11607-2:2020/A11:2022, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EU Certificate No.: G11 088308 0023 Rev. 01

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. 2777/11461-05/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: 2025-06-24 **Platné do:** 2027-06-23 **Verzia:** 001

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,
9 Straits View, Singapore 018937, Singapore
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: Is. osztály az orvostechnikai eszközökről szóló (EU) 2017/745 rendelet szerint
III. kategória az egyéni védőeszközökről szóló (EU) 2016/425 rendelet szerint

Alapvető UDI-DI: 9001570N*F-047OB-S-3TK

sempermed safe sterile

Méretek	X-Small	Small	Medium	Large	X-Large	XX-Large
Cikkszámok		3000016225	3000016226	3000016227	3000016228	

Ezennel kizárólagos felelősségünk mellett kijelentjük, hogy a CE 0123 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 megfelelősségi értékelés a IX. mellékleten alapul.

Alkalmazott szabványok: ASTM D3577-19(2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A1:2022, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009, EN 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015/A1:2023, EN ISO 11607-1:2020/A11:2022, EN ISO 11607-2:2020/A11:2022, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EU Certificate No.: G11 088308 0023 Rev. 01

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:2777/11461-05/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 : 2025-06-24 **Érvényes:** 2027-06-23 **Verzió:** 001

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

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

To potrdilo velja za naslednji izdelek:

Sterilne preiskovalne zaščitne rokavice za enkratno uporabo
Klasifikacija: Razred Is v skladu z Uredbo o medicinskih pripomočkih (EU) 2017/745
Kategorija III v skladu z Uredbo OVO (EU) 2016/425

Osnovni UDI-DI: 9001570N*F-047OB-S-3TK

sempermed safe sterile

Velikosti	X-Small	Small	Medium	Large	X-Large	XX-Large
Številke izdelkov		3000016225	3000016226	3000016227	3000016228	

S to izključno odgovornostjo izjavljamo, da zgoraj navedeni izdelki z znako CE 0123 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 IX.

Uporabljeni standardi: ASTM D3577-19(2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A1:2022, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009, EN 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015/A1:2023, EN ISO 11607-1:2020/A11:2022, EN ISO 11607-2:2020/A11:2022, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EU Certificate No.: G11 088308 0023 Rev. 01

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 osebni zaščitni opremi, ki je predmet certifikata o EU-pregledu tipa št. 2777/11461-05/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: 2025-06-24 **Veljavno do:** 2027-06-23 **Različica:** 001

EU IZJAVA O SUKLADNOSTI

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

Sterilne zaštitne rukavice za pregled za jednokratnu uporabu
Klasifikacija: Klasa I.s prema Direktivi o medicinskim proizvodima (EU) 2017/745
Kategorija III. prema Uredbi o osobnoj zaštitnoj opremi (EU) 2016/425

Osnovni UDI-DI: 9001570N*F-047OB-S-3TK

sempermed safe sterile

Veličine	X-Small	Small	Medium	Large	X-Large	XX-Large
Br. artikla		3000016225	3000016226	3000016227	3000016228	

Ovim putem izjavljujemo pod punom odgovornošću da su proizvodi s CE 0123 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 IX.

Primijenjene norme: ASTM D3577-19(2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A1:2022, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009, EN 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015/A1:2023, EN ISO 11607-1:2020/A11:2022, EN ISO 11607-2:2020/A11:2022, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EU Certificate No.: G11 088308 0023 Rev. 01

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.2777/11461-05/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: 2025-06-24 **Vrijedi do:** 2027-06-23 **Verzija:** 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.
#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:

Sterylne rękawice medyczne i ochronne jednorazowego użytku

Klasyfikacja: Klasa Is 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: 9001570N*F-047OB-S-3TK

sempermed safe sterile

Rozmiary	X-Small	Small	Medium	Large	X-Large	XX-Large
Numery artykułów		3000016225	3000016226	3000016227	3000016228	

Na własną odpowiedzialność oświadczamy niniejszym, że opisany powyżej produkt z oznakowaniem CE 0123 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 IX.

Zastosowane normy: ASTM D3577-19(2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A1:2022, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009, EN 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015/A1:2023, EN ISO 11607-1:2020/A11:2022, EN ISO 11607-2:2020/A11:2022, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EU Certificate No.: G11 088308 0023 Rev. 01

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 2777/11461-05/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: 2025-06-24 **Data ważności:** 2027-06-23 **Wersja:** 001

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,
9 Straits View, Singapore 018937, Singapore
sempermed@harpsglobal.com
SRN: SG-MF-000001645

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

Acest certificat este valabil pentru următoarele produse:

Mânușă de consult și de protecție sterilă de unică folosință
clasificare: Clasa Is conform regulamentului (UE) 2017/745 privind produsele medicale
Categoria III conform regulamentului (UE) 2016/425 privind EPP

UDI-DI de bază: 9001570N*F-047OB-S-3TK

sempermed safe sterile

mărimi	X-Small	Small	Medium	Large	X-Large	XX-Large
Numerele de articole		3000016225	3000016226	3000016227	3000016228	

Prin prezenta declarăm pe propria răspundere că produsele marcate CE 0123 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 IX.

Standarde aplicate: ASTM D3577-19(2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A1:2022, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009, EN 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015/A1:2023, EN ISO 11607-1:2020/A11:2022, EN ISO 11607-2:2020/A11:2022, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EU Certificate No.: G11 088308 0023 Rev. 01

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. 2777/11461-05/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: 2025-06-24 **Valabil până în:** 2027-06-23 **Versiune:** 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.
#08-10A Marina One West Tower,
9 Straits View, Singapore 018937, Singapore
sempermed@harpsglobal.com
SRN: SG-MF-000001645

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

Το παρόν πιστοποιητικό ισχύει για τα ακόλουθα προϊόντα:

Αποστειρωμένο γάντι εξέτασης και προστατευτικό γάντι μιας χρήσης
Ταξινόμηση: Κατηγορία Is σύμφωνα με την Κανονισμό (EU) 2017/745 περί ιατροτεχνολογικών προϊόντων
Κατηγορία II σύμφωνα με τον Κανονισμό (ΕΕ) 2016/425 περί ΜΑΠ

βασικό UDI-DI: 9001570N*F-047OB-S-3TK

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Μεγέθη	X-Small	Small	Medium	Large	X-Large	XX-Large
Αριθμοί προϊόντος		3000016225	3000016226	3000016227	3000016228	

Δια του παρόντος βεβαιώνουμε υπεύθυνα ότι τα προϊόντα με σήμανση CE 0123 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 βασίζεται στο παράρτημα IX.

Εφαρμοζόμενα πρότυπα: ASTM D3577-19(2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A1:2022, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009, EN 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015/A1:2023, EN ISO 11607-1:2020/A11:2022, EN ISO 11607-2:2020/A11:2022, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EU Certificate No.: G11 088308 0023 Rev. 01

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. 2777/11461-05/E01-01 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 : 2025-06-24 **Ισχύει έως:** 2027-06-23 **Εκδοχή:** 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.
#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:

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

Базовият UDI-DI: 9001570N*F-047OB-S-3TK

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Размери	X-Small	Small	Medium	Large	X-Large	XX-Large
Номера на артикулите		3000016225	3000016226	3000016227	3000016228	

С настоящето потвърждаваме при самостоятелна отговорност, че продуктите с маркировка CE 0123 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 IX.

Приложими норми: ASTM D3577-19(2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A1:2022, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009, EN 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015/A1:2023, EN ISO 11607-1:2020/A11:2022, EN ISO 11607-2:2020/A11:2022, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EU Certificate No.: G11 088308 0023 Rev. 01

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 № 2777/11461-05/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: 2025-06-24 **Важи до:** 2027-06-23 **Версия:** 001

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,
9 Straits View, Singapore 018937, Singapore
sempermed@harpsglobal.com
SRN: SG-MF-000001645

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

Bu sertifika aşağıdaki ürün için geçerlidir:

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

Temel UDI-DI: 9001570N*F-047OB-S-3TK

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Boyutlar	X-Small	Small	Medium	Large	X-Large	XX-Large
Ürün numaraları		3000016225	3000016226	3000016227	3000016228	

Yukarıda açıklanan CE 0123 işaretli ürünün (EU) 2017/745/AET 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 IX'a dayanmaktadır.
Uygulamalı standartlar: ASTM D3577-19(2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A1:2022, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009, EN 556-1:2001 + AC:2006, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 11137-1:2015 + A2:2019, EN ISO 11137-2:2015/A1:2023, EN ISO 11607-1:2020/A11:2022, EN ISO 11607-2:2020/A11:2022, EN ISO 11737-1:2018 + A1:2021, EN ISO 11737-2:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, ID No. 0123, EU Certificate No.: G11 088308 0023 Rev. 01

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. 2777/11461-05/E01-01 veriliş :

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

Birgit Sebauer
Person Responsible for Regulatory Compliance

Larissa Rieger
Head of Product Management

Veriliş tarihi: 2025-06-24 **Son geçerlilik tarihi:** 2027-06-23 **Sürüm:** 001