

EU DECLARATION OF CONFORMITY

PERSONAL PROTECTIVE EQUIPMENT REGULATION (EU) 2016/425

Legal Manufacturer

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

Authorized representative in the EU

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

This certificate is valid for the following product:

Non-sterile protective glove

Classification: Category I according to PPE Regulation (EU) 2016/425

sempertip yellow

Sizes	X-Small	Small	Medium	Large	X-Large	XX-Large
Article codes	-	818503074	818503084	818503094	818503104	-
	-	3000006265	3000006266	3000006267	3000006268	-

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.

Applied standards: EN ISO 21420:2020



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Issued: 2025-08-13

Expires: 2027-08-12

Version: 002

EU-KONFORMITÄTSERKLÄRUNG

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:

Nicht-steriler Schutzhandschuh

Klassifizierung: Kategorie I gemäß PSA Verordnung (EU) 2016/425

sempertip yellow

Größen	X-Small	Small	Medium	Large	X-Large	XX-Large
Artikelnummern	-	818503074	818503084	818503094	818503104	-
	-	3000006265	3000006266	3000006267	3000006268	-

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.

Angewandte Normen: EN ISO 21420:2020



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Ausgestellt am: 2025-08-13

Gültig bis: 2027-08-12

Version: 002

DÉCLARATION UE DE CONFORMITÉ

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 de protection non-stérile

Classification : Catégorie I selon le règlement EPI (UE) 2016/425

sempertip yellow

Tailles	X-Small	Small	Medium	Large	X-Large	XX-Large
Numéros d'article	-	818503074	818503084	818503094	818503104	-
	-	3000006265	3000006266	3000006267	3000006268	-

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.



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Délivré le : 2025-08-13

Valable jusqu'au :

2027-08-12

Version: 002

DICHIARAZIONE DI CONFORMITÀ UE

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 protettivo non sterile

Classificazione: Categoria I secondo il regolamento (UE) 2016/425 del PPE

sempertip yellow

Misure	X-Small	Small	Medium	Large	X-Large	XX-Large
Codici articolo	-	818503074 3000006265	818503084 3000006266	818503094 3000006267	818503104 3000006268	- -

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.



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Rilasciato : 2025-08-13

Scade: 2027-08-12

Version: 002

EU-CONFORMITEITSVERKLARING

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:

Niet-steriele beschermende handschoen

Classificatie: Categorie I volgens PBM-verordening (EU) 2016/425

sempertip yellow

Maten	X-Small	Small	Medium	Large	X-Large	XX-Large
Artikelnummers	-	818503074	818503084	818503094	818503104	-
	-	3000006265	3000006266	3000006267	3000006268	-

Hierbij verklaren wij onder uitsluitende verantwoordelijkheid, dat de bovengenoemde CE-gemarkeerde producten voldoen aan de relevante bepalingen van de Verordening (EU) 2016/425 betreffende persoonlijke beschermingsmiddelen.



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Uitgegeven op: 2025-08-13

Geldig tot: 2027-08-12

Versie: 002

DECLARACIÓN UE DE CONFORMIDAD

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 de protección no estéril

Clasificación: Categoría I según el Reglamento EPI (UE) 2016/425

sempertip yellow

Tamaños	X-Small	Small	Medium	Large	X-Large	XX-Large
Número de artículo	-	818503074	818503084	818503094	818503104	-
	-	3000006265	3000006266	3000006267	3000006268	-

Por la presente confirmamos, bajo nuestra exclusiva responsabilidad, que los productos con la marca CE antes mencionados cumplen con las disposiciones aplicables del Reglamento (UE) 2016/425 sobre equipos de protección personal.



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Expedido el: 2025-08-13

Válido hasta: 2027-08-12

Versión: 002

DECLARAÇÃO DE CONFORMIDADE UE

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 proteção não estéril

Classificação: Categoria I de acordo com o regulamento EPI (UE) 2016/425

sempertip yellow

Tamanhos	X-Small	Small	Medium	Large	X-Large	XX-Large
Números de artigo	-	818503074	818503084	818503094	818503104	-
	-	3000006265	3000006266	3000006267	3000006268	-

Declaramos desta forma, sob a nossa exclusiva responsabilidade, que os produtos com a marca CE acima mencionados cumprem as disposições relevantes do regulamento (UE) 2016/425 para Equipamentos de Proteção Individual.



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Emitido em: 2025-08-13

Válido até: 2027-08-12

Versão: 002

EU-FÖRSÄKRAN OM ÖVERENSSTÄMMELSE

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:

Icke-steril skyddshandske

Klassificering: Kategori I enligt EU-förordning för personlig skyddsutrustning (PPE) 2016/425

sempertip yellow

Storlekar	X-Small	Small	Medium	Large	X-Large	XX-Large
Artikelnummer	-	818503074	818503084	818503094	818503104	-
	-	3000006265	3000006266	3000006267	3000006268	-

Vi förklarar härmed under eget exklusivt ansvar att ovan beskrivna, CE-märkade produkt stämmer överens med tillämpliga bestämmelser i EU-förordningen 2016/425 för personlig skyddsutrustning.



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Daterad : 2025-08-13

Giltig till:

2027-08-12

Version: 002

EU-OVERENSSTEMMELSESERKLÆRING

FORORDNING (EU) 2016/425 FOR PERSONLIGE VÆRNEMIDLER

Producent

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

EU-befuldmægtigede

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

Dette certifikat er gyldigt for følgende produkter:

Ikke-steril beskyttelseshandske

Klassificering: Kategori I jævnfør PVM-lovgivningen (EU) 2016/425

sempertip yellow

Størrelser	X-Small	Small	Medium	Large	X-Large	XX-Large
Artikelnumre	-	818503074	818503084	818503094	818503104	-
	-	3000006265	3000006266	3000006267	3000006268	-

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.



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Udstedt den: 2025-08-13

Gyldig til: 2027-08-12

Version: 002

EU-SAMSVARSERKLÆRING

EU-FORORDNING OM PERSONLIG VERNEUTSTYR 2016/425

Juridisk produsent

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

Autorisert representant i EU

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

Dette sertifikatet er gyldig for følgende produkt:

Ikke-steril beskyttelseshanske

Klassifisering: Kategori I i henhold til PVU-forordningen (EU) nr. 2016/425

sempertip yellow

Størrelser	X-Small	Small	Medium	Large	X-Large	XX-Large
Artikkelnumre	-	818503074	818503084	818503094	818503104	-
	-	3000006265	3000006266	3000006267	3000006268	-

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.



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Utstedt: 2025-08-13

Utløper: 2027-08-12

Versjon: 002

EU-VAATIMUSTENMUKAISUUSVAKUUTUS

HENKILÖNSUOJAIMISTA ANNETTU ASETUS (EU) 2016/425

Valmistaja

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

EU:n valtuutettu edustaja

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

Tämä sertifiikaatti koskee seuraavia tuotteita:

Ei-steriili suojakäsine

Luokitus: Luokka I henkilönsuojaimista annetun asetuksen (EU) 2016/425 mukaisesti

sempertip yellow

Koot	X-Small	Small	Medium	Large	X-Large	XX-Large
Tuotenumerot	-	818503074	818503084	818503094	818503104	-
	-	3000006265	3000006266	3000006267	3000006268	-

Täten vahvistamme yksinomaisella vastuullamme, että CE-merkityt tuotteet vastaavat henkilönsuojaimista annetun asetuksen (EU) 2016/425 mukaisia perustavanlaatuisia vaatimuksia.



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Laadittu : 2025-08-13

Voimassa (asti):

2027-08-12

Versio: 002

ES ATITIKTIES DEKLARACIJA

REGLAMENTAS (ES) 2016/425 DĖL ASMENINIŲ APSAUGOS PRIEMONIŲ

Gamintojas

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

ES įgaliotas asmuo

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

Šis sertifikatas galioja toliau nurodytiems produktams:

Nesterilios apsauginės pirštinės

Klasifikacija: I kategorija pagal reglamentą (ES) 2016/425 dėl asmeninių apsaugos priemonių

sempertip yellow

Dydžiai	X-Small	Small	Medium	Large	X-Large	XX-Large
Prekių numeriai	-	818503074	818503084	818503094	818503104	-
	-	3000006265	3000006266	3000006267	3000006268	-

Prisiimdami visą atsakomybę, šiuo dokumentu patvirtiname, kad anksčiau paminėti CE paženklininti produktai atitinka svarbiausius reglamentą dėl asmeninių apsaugos priemonių (ES) 2016/425 reikalavimus.



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Išduota : 2025-08-13

Galioja iki: 2027-08-12

Versija: 002

ES ATBILSTĪBAS DEKLARĀCIJA

REGULA (ES) 2016/425 PAR INDIVIDUĀLAJĪEM AIZSARDZĪBAS LĪDZEKĻIEM

Likumīgais ražotājs

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

Pilnvarotais pārstāvis ES

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

Šis sertifikāts ir derīgs šādam produktam:

Nesterili aizsargcimdi

Klasifikācija: I kategorija saskaņā ar IAL Regulu (ES) 2016/425

sempertip yellow

Izmēri	X-Small	Small	Medium	Large	X-Large	XX-Large
Artikula numurs	-	818503074	818503084	818503094	818503104	-
	-	3000006265	3000006266	3000006267	3000006268	-

Ar šo mēs apliecinām, ka iepriekš aprakstītais produkts ar CE marķējumu atbilst Regulas (ES) 2016/425 par individuālajiem aizsardzības līdzekļiem piemērojamajiem noteikumiem.



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Izdots : 2025-08-13

Derīgs līdz:

2027-08-12

Versija: 002

ELI VASTAVUSDEKLARATSIOON

ISIKUKAITSEVAHENDITE MÄÄRUS (EL) 2016/425

Seaduslik tootja

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

Volitatud esindaja EL-is

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

See sertifikaat kehtib järgmistele toodetele:

Mittesteriilne kaitsekinnas

Klassifikatsioon: I kategooria kooskõlas isikukaitsevahendite määrusega (EL) 2016/425

sempertip yellow

Suurused	X-Small	Small	Medium	Large	X-Large	XX-Large
Tootenumbriid	-	818503074	818503084	818503094	818503104	-
	-	3000006265	3000006266	3000006267	3000006268	-

Kinnitame oma ainuvastutusel, et eespool nimetatud CE-märgistusega tooted on kooskõlas isikukaitsevahendite määruse (EL) 2016/425 põhisätetega.



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Välja antud : 2025-08-13

Aegub: 2027-08-12

Versioon: 002

EU PROHLÁŠENÍ O SHODĚ

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 zmocněný zástupce

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

Tento certifikát je platný pro následující produkty:

Nesterilní ochranná rukavice

Klasifikace Kategorie I podle nařízení o OOP (EU) 2016/425

sempertip yellow

Velikosti	X-Small	Small	Medium	Large	X-Large	XX-Large
Číslo produktu	-	818503074	818503084	818503094	818503104	-
	-	3000006265	3000006266	3000006267	3000006268	-

Tímto potvrzujeme s výlučnou odpovědností, že výše uvedené produkty označené jako CE souhlasí s příslušnými ustanoveními nařízení (EU) 2016/425 pro Osobní ochranné prostředky.



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Vystaveno dne: 2025-08-13

Platné do: 2027-08-12

Verze: 002

EÚ VYHLÁSENIE O ZHODE

NARIADENIE (EÚ) 2016/425 O OSOBNÝCH OCHRANNÝCH PROSTRIEDKoch

Výrobca

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

Splnomocnenec pre EÚ

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

Tento certifikát je platný pre nasledujúce body:

Nesterilné ochranné rukavice

Klasifikácia: Kategória I podľa Nariadenia o osobných ochranných pomôckach (EÚ) 2016/425

sempertip yellow

Veľkosti	X-Small	Small	Medium	Large	X-Large	XX-Large
Výrobné čísla	-	818503074	818503084	818503094	818503104	-
	-	3000006265	3000006266	3000006267	3000006268	-

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.



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Vyhotovené dňa: 2025-08-13

Platné do: 2027-08-12

Verzia: 002

EU-MEGFELELŐSÉGI NYILATKOZAT

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:

Nem steril védőkesztyű

Osztályozás: I. kategória az egyéni védőeszközökről szóló (EU) 2016/425 rendelet szerint

sempertip yellow

Méret	X-Small	Small	Medium	Large	X-Large	XX-Large
Cikkszámok	-	818503074 3000006265	818503084 3000006266	818503094 3000006267	818503104 3000006268	- -

Ezennel kizárólagos felelősségünk mellett kijelentjük, hogy a fent említett CE-jelzésű termékek megfelelnek az egyéni védőeszközökről szóló 2016/425/EU rendelet vonatkozó rendelkezéseinek.



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Kelt : 2025-08-13

Érvényes: 2027-08-12

Verzió: 002

IZJAVA EU O SKLADNOSTI

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

Pooblaščen zastopnik v EU

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

To potrдіlo velja za naslednji izdelek:

Nesterilne zaščitne rokavice

Klasifikacija: Kategorija I v skladu z Uredbo OVO (EU) 2016/425

sempertip yellow

Velikosti	X-Small	Small	Medium	Large	X-Large	XX-Large
Številke izdelkov	-	818503074	818503084	818503094	818503104	-
	-	3000006265	3000006266	3000006267	3000006268	-

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.



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Izdano dne: 2025-08-13

Veljavno do: 2027-08-12

Različica: 002

EU IZJAVA O SUKLADNOSTI

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:

Nesterilne zaštitne rukavice

Klasifikacija: Kategorija I. prema Uredbi o osobnoj zaštitnoj opremi (EU) 2016/425

sempertip yellow

Veličine	X-Small	Small	Medium	Large	X-Large	XX-Large
Br. artikla	-	818503074	818503084	818503094	818503104	-
	-	3000006265	3000006266	3000006267	3000006268	-

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.



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Izdano dana: 2025-08-13

Vrijedi do: 2027-08-12

Verzija: 002

DEKLARACJA ZGODNOŚCI UE

ROZPORZĄDZENIE W SPRAWIE ŚRODKÓW OCHRONY INDYWIDUALNEJ (UE) 2016/425

Producent

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

Autoryzowany przedstawiciel w UE

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

Niniejszy certyfikat obowiązuje w odniesieniu do następującego produktu:

Niesterylne rękawice ochronne

Klasyfikacja: Kategoria I zgodnie z rozporządzeniem (UE) 2016/425 w sprawie środków ochrony indywidualnej

sempertip yellow

Rozmiary	X-Small	Small	Medium	Large	X-Large	XX-Large
Numery artykułów	-	818503074	818503084	818503094	818503104	-
	-	3000006265	3000006266	3000006267	3000006268	-

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.



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Data wydania: 2025-08-13

Data ważności: 2027-08-12

Wersja: 002

DECLARAȚIA DE CONFORMITATE UE

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:

Mănușă de protecție nesterilă

clasificare: Categoria I conform regulamentului (UE) 2016/425 privind EPP

sempertip yellow

mărimi	X-Small	Small	Medium	Large	X-Large	XX-Large
Numerele de articole	-	818503074	818503084	818503094	818503104	-
	-	3000006265	3000006266	3000006267	3000006268	-

Prin prezenta declarăm pe propria răspundere că produsele marcate CE indicate mai sus corespund cerințelor de bază (EU) 2016/425 pentru echipamente personale de protecție.



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Eliberat la data de: 2025-08-13

Valabil până în: 2027-08-12

Versiune: 002

ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ ΕΕ

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:

Μη αποστειρωμένο προστατευτικό γάντι

Ταξινόμηση: Κατηγορία I σύμφωνα με τον Κανονισμό (ΕΕ) 2016/425 περί ΜΑΠ

sempertip yellow

Μεγέθη	X-Small	Small	Medium	Large	X-Large	XX-Large
Αριθμοί προϊόντος	-	818503074	818503084	818503094	818503104	-
	-	3000006265	3000006266	3000006267	3000006268	-

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.



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Εκδόθηκε : 2025-08-13

Ισχύει έως:

2027-08-12

Εκδοχή: 002

ЕС ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ

РЕГЛАМЕНТ (EU) 2016/425 ЗА ЛИЧНИТЕ ПРЕДПАЗНИ СРЕДСТВА

Производител

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

Упълномощен представител в ЕС

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

Настоящият сертификат важи за следните продукти:

Нестерилна предпазна ръкавица

Класификация: Категория I съгл. Регламент за ЛПС (EU) 2016/425

sempertip yellow

Размери	X-Small	Small	Medium	Large	X-Large	XX-Large
Номера на артикулите	-	818503074	818503084	818503094	818503104	-
	-	3000006265	3000006266	3000006267	3000006268	-

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.



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Издадено на: 2025-08-13

Важи до: 2027-08-12

Версия: 002

AB UYGUNLUK BEYANI

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:

Steril olmayan koruyucu eldiven

Sınıflandırma: KKE Yönetmeliği (AB) 2016/425 uyarınca Kategori I

sempertip yellow

Boyutlar	X-Small	Small	Medium	Large	X-Large	XX-Large
Ürün numaraları	-	818503074	818503084	818503094	818503104	-
	-	3000006265	3000006266	3000006267	3000006268	-

Yukarıda açıklanan CE işaretli ürünün, (AB) 2016/425 sayılı Kişisel Koruyucu Ekipman Yönetmeliğinin belirleyici hükümlerine uygun olduğunu tek sorumluluğumuzda beyan ederiz.



Birgit Sebauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Veriliş tarihi: 2025-08-13

Son geçerlilik tarihi: 2027-08-12

Sürüm: 002