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

Brand owner
Norengros AS
Fyrstikkalleen 3A
N-0661 Oslo / Norway

This certificate is valid for the following product:

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

Basic UDI-DI: 9001570N*F-035WH-N-3WF

Tendercare Nitrile White

Sizes	X-Small	Small	Medium	Large	X-Large	XX-Large
Article codes	-	3000003338	3000003339	3000003340	3000003341	-
	-	111247	111248	111249	287497	

We hereby declare under sole responsibility that the CE marked product described above conforms to the requirements of the regulation for medical devices (EU) 2017/745.

Declaration based on Annex IV. Classification according to rule 5, Annex VIII. The conformity assessment is based on Annex II.

Applied standards: ASTM D3578-19 (2023), ASTM D6319-19 (2023) or ASTM D5250-19 (2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A1:2022, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

We hereby declare under sole responsibility that the CE marked product described above conforms with the applicable provisions of Regulation (EU) 2016/425 on personal protective equipment and is identical to the personal protective equipment which is subject to EU Type Examination Certificate No. 2777/11464-03/E13-01 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

Birgit Sebauer
Person Responsible for Regulatory Compliance

Larissa Rieger
Head of Product Management

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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
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Autorisert representant i EU
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1100 Wien, Austria
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SRN: AT-AR-000040870

Merkeier
Norengros AS
Fyrstikkalleen 3A
N-0661 Oslo / Norway

Dette sertifikatet er gyldig for følgende produkt:

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

Basic UDI-DI: 9001570N*F-035WH-N-3WF

Tendercare Nitrile White

Størrelser	X-Small	Small	Medium	Large	X-Large	XX-Large
Artikkelnumre	-	3000003338	3000003339	3000003340	3000003341	-
	-	111247	111248	111249	287497	

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

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

Anvendte standarder: ASTM D3578-19 (2023), ASTM D6319-19 (2023) or ASTM D5250-19 (2023), ASTM F1671/F1671M-22, EN ISO 20417:2021, EN 455-1:2020+A1:2022, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2023, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006, Directive 2008/98/EC

Vi erklærer herved under eneansvar at det CE-merkede produktet som er nevnt ovenfor oppfyller de relevante bestemmelsene i EU-forordning nr. 2016/425 om personlig verneutstyr og er gjenstand for EU-typeprøvesertifikat nr. 2777/11464-03/E13-01 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

Birgit Sebauer
Person Responsible for Regulatory Compliance

Larissa Rieger
Head of Product Management

Utstedt: 2025-07-02 **Utløper:** 2027-07-01 **Versjon:** 002