

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-030VB-N-3RB

Tendercare Nitrile Blue

Sizes	X-Small	Small	Medium	Large	X-Large	XX-Large
Article codes	-	3000007094	3000007095	3000007096	3000007097	-
	-	111251	111252	111253	287498	

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. 2777/11466-03/E22-01 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

Issued: 2025-07-02

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2027-07-01

Version: 002

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

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-030VB-N-3RB

Tendercare Nitrile Blue

Størrelser	X-Small	Small	Medium	Large	X-Large	XX-Large
Artikkelnumre	-	3000007094	3000007095	3000007096	3000007097	-
	-	111251	111252	111253	287498	

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. 2777/11466-03/E22-01 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 Seibauer
Person Responsible for Regulatory Compliance



Larissa Rieger
Head of Product Management

Utstedt: 2025-07-02

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