



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:

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

Basic UDI-DI: 9001570NOF-035BK-N-3YN

semperguard sapphire XP black

Sizes	X-Small	Small	Medium	Large	X-Large	XX-Large
Article codes	3000016209	3000016210	3000016211	3000016212	3000016213	3000016214

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. 2777/11464-04/E04-01 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

Andreas Wöss
 Person responsible for Regulatory Compliance

Birgit Sebauer
 Head of Quality & Regulatory Affairs

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