

**EU Declaration of Conformity according to the Medical Devices Regulation (EU) 2017/745 and the
PPE Regulation (EU) 2016/425**

The manufacturer:
Ampri Handelsgesellschaft mbH
Benzstr. 16
21423 Winsen (Luhe)
Germany
declares under its own responsibility that

art. no.
01198 XS-XXL BLUE ECO PLUS
Nitrile examination gloves
Basic-UDI-DI: 4044941001002RC

- 1) Complies with the requirements of regulation (EU) 2017/745 and the harmonised standards:

EN 455-1:2020	EN 455-2:2015	EN 455-3:2015	EN 455-4:2009
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This product is a Class 1 medical device according to the classification in Annex VIII.

and

- 2) complies with the requirements of regulation (EU) 2016/425 and the harmonized standards of

EN ISO 374-1:2016+A1:2018		
EN ISO 374-5:2016	EN 420:2003+A1:2009	

and the standards

EN ISO 374-4:2019	ISO 16604:2004		
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This product is a PPE of category III in accordance with attachment I of the regulation and is identical with the PPE which was subject to the EU type examination certificate no.

2777/12003-01/E03-01

issued by Satra, identification number 2777 and that is subject to the procedure according to Modul C2 of the regulation (EU) 2016/425 under the control of the notified body Satra (2777 identification number)

Technical documentation is available to prove this is accordance with the requirements.

Winsen, 06.07.2021



ppa. Stephan Welzin
Head of Quality Management & Operational Purchasing

This Declaration of Conformity is valid until 21.02.2024



CERTIFICATE

Certificate no. 11075

AMPri

AMPri Handelsgesellschaft mbH

Benzstraße 16

DE-21423 Winsen/Luhe

QS ZÜRICH AG certifies that the management system of the above mentioned company and location(s) has been evaluated and meets the requirements established by the following rules:

ISO 9001: 2015

The management system includes:

**Trade with medical products
and protection equipment and consulting**

During the period of validity of this certificate, the management system of the company must always comply with the requirements of the certified standards.

For updated amendments within the scope of certification of the present certificate, please refer to

<http://www.quality-service.ch/>



First certification date:

23.10.2014

Date of issue:

22.10.2020

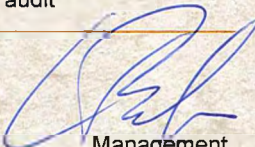
Expiration date:

22.10.2023

Subject to successful surveillance audit

QS ZÜRICH AG
P.O. Box 6335
CH-8050 Zürich
info@quality-service.ch




Management



CERTIFICATE

Certificate no. 14062

AMPri

AMPri Handelsgesellschaft mbH

Benzstraße 16

DE-21423 Winsen/Luhe

QS ZÜRICH AG certifies that the management system of the above mentioned company and location(s) has been evaluated and meets the requirements established by the following rules:

EN ISO 13485: 2016

The management system includes:

**Trade with medical products
and protection equipment and consulting**

During the period of validity of this certificate, the management system of the company must always comply with the requirements of the certified standards.

For updated amendments within the scope of certification of the present certificate, please refer to

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Management