



**EU Declaration of Conformity according to the Medical Devices Directive 93/42/EEC
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. 01197 XS-XXL Blue Basic Plus Nitrile Gloves

- 1) Complies with the requirements of Annex VII of Directive 93/42/EEC and the harmonised standards; EN 455-1:2000, EN 455-2:2015, EN 455-3:2015 and EN 455-4:2009.

This product is a Class I medical device according to the classification in Annex IX.
and

- 2) complies with the requirements of regulation (EU) 2016/425 and the harmonized standards EN ISO 374-1:2016, EN ISO 374-5:2016, EN 420:2003+A1:2009 and the standards EN 374-4:2013

This product is a PPE of category 3 in accordance with attachment I of the regulation and is identical with that PSA which was subject to the EG type examination certificate No. 0321/10015-01/E00-00 issued by the Satra identification number 0321 and that is subject to the procedure according to modul C2 of regulation (EU) 2016/425 under the control of the notified body Satra (0321 identification number).

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

Winsen, 30/06/2018



ppa. Stephan Welzin
Head of Quality Management & Operational Purchasing

This Declaration of Conformity is valid until 22.04.2020