

**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  
SRN: DE-MF-000007622  
declares under its own responsibility that  
art. no.  
**29240 (118-065) XS-L RUCK Grün**  
**Nitrile examination gloves**  
Basic-UDI-DI: 4044941001002RC

- 1) Complies with the requirements of regulation (EU) 2017/745 and the 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.

2777/10126-02/E11-01

issued by Satra, identification number 2777 and that is subject to the procedure according to Modul D of the regulation (EU) 2016/425 under the control of the notified body SGS (0598 identification number)

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

Winsen, 12.10.2021



ppa. Stephan Welzin  
Head of Quality Management & Operational Purchasing

This Declaration of Conformity is valid until 21.04.2023