

**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.  
**01033 XS-XL BASIC TOUCH**  
**Latex examination gloves**  
 Basic-UDI-DI: 4044941001001RA

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

EN 455-1:2000	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 374-4:2019		
EN ISO 374-5:2016	EN 420:2003+A1:2009		

and the standards

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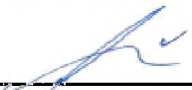
This product is a PPE of category III in accordance with attachment I of the regulation and is identical with the PPE which was subject to the EU type examination certificate no.

2777/11949-01/E06-01

issued by Satra , identification number 2777 and that is subject to the procedure according to Modul C2 2777/11949-01/E06-01 Satra (2777 identification number)

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

Winsen, 26.05.2020



ppa. Stephan Welzin  
 Head of Quality Management & Operational Purchasing

This Declaration of Conformity is valid until 14.02.2024