

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