



**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.  
**14-011 XS-XXL Style Purple**  
**Latex examination 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	EN 455-4:2009
---------------	---------------	---------------	---------------

This product is a Class 1 medical device according to the classification in Annex IX.

and

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

EN ISO 374-1:2016+A1:20			
EN ISO 374-5:2016	EN 420:2003+A1:2009		

and the standards

EN 374-4:2013	ISO 16604:2004		
---------------	----------------	--	--

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.

GB 18/961189

issued by SGS, identification number 0598 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, 13.02.2020

ppa. Stephan Welzin  
Head of Quality Management & Operational Purchasing

This Declaration of Conformity is valid until 25.05.2020