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.

A2110850-XS, A2110851-S, A2110852-M, A2110853-L, A2110854-XL (39-048) TMS Comfort PLUS 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. 2777/11949-01/E16-01
issued by Satra , identification number 2777 and that is subject to the procedure according to Modul C2 of the regulation (EU) 2016/425 under the control of the notified body Satra (2777 identification number)

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

Winsen, 18.02.2020

i.V.

ppa. Stephan Welzin
Head of Quality Management & Operational Purchasing

This Declaration of Conformity is valid until 25.05.2025

revision 01