**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.

**01251 S-XL MED COMFORT VITRIL (Vinyl-Nitrile-Mixture)**
**Vinyl 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 ISO 21420:2020 | | |

and the standards

| | | | |
|---|---|---|---|
| EN 374-4:2019 | 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.
2777/15012-01/E05-01
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 2777/15012-01/E05-01

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

Winsen, 01.03.2021

i.V.

ppa. Stephan Welzin
Head of Quality Management & Operational Purchasing

This Declaration of Conformity is valid until 25.05.2021