



## EU Declaration of conformity

in accordance to  
93/42/EEC and Regulation  
(EU) 2016/425

We,

**Medsorg GmbH  
Lahnstraße 30**

**45478 Mülheim an der Ruhr**

Declare on our own responsibility that the following group of products or products:

- **Nitril- Untersuchungshandschuhe (Art Nr. 8810, 8820, 8830, 8840)**

Which deals with the declaration, be conform with the conformity assessment procedure set out in Annex VII of 93/42 EEC for medical devices from September 2007 and fulfil the basic requirements of annex I.

The products are class I, Rule 1, according to annex IX of the 93/42/EEC

and

be conform with the conformity assessment procedure of Regulation (EU) 2016/425 and complies with the harmonised standards

- EN ISO 420:2003+A1:2009
- EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN ISO 374-4:2019, EN ISO 374-5:2016

The product is PPE (personal protection equipment) Category III according to Annex I of the Regulation (EU) 2016/425. This is identical to the PPE, that was the subject of the EU type examination certificate No. ## by the notified body Satra Technology Europe Ltd, Bracetown Business Park, Clonee, Dublin Ireland (CE2777) and the procedure according to module C2 of Regulation (EU) 2016/425, which is under control of the notified body Satra Technology Europe Ltd, Bracetown Business Park, Clonee, Dublin Ireland (CE2777).

This declaration is valid from the date of issue for the products placed on the market.

This document is valid until: 25.05.2021.

  
  
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Joel Ekho  
Authorized signatory  
(legally binding signature)