

## Declaration of Conformity

We,

**BODY PRODUCTS RELAX Pharma und Kosmetik GmbH**  
Alfred-Nobel-Straße 1-3  
D-50226 Frechen, Germany

declare on our own sole responsibility that the following described medical devices

<b>Item code</b>	2916001 - 2916004
<b>Description</b>	RUCK Superstretch Handschuhe
<b>Type</b>	Vinyl examination gloves, non-sterile, powder free, Class I

are in conformity with the essential requirements of the EU Regulation 2017/745, including its additions and amendments as well as the technical documentation and the conformity assessment procedure according to Annex IV.

In accordance to the classification provisions by rule 1 and 5 of EU Regulation 2017/745 Annex VIII the products are certified as medical device class 1.

Furthermore they comply with the following harmonized standards:

EN 455-1:2000  
EN 455-2:2009  
EN 455-3:2000  
EN 455-4:2009  
EN 1041  
EN ISO 15223-1

With regard to the use and utilization of the above mentioned product, we emphasize, that the instruction for use (see labelling on packaging) as well as the appropriate application and safety rules shall be followed in particular.

The user of the product bears the sole responsibility caused by improper usage or other than the intended use.

In terms of the evidence of conformity all relevant documents are filed in our premises in accordance to current regulations and available for the authorities at any time.

The declaration is valid until 31/03/2023

Frechen, the 01/07/2020  
Place, date of exhibition



Ralf Hucklenbroich, Managing Director