

## EU DECLARATION OF CONFORMITY

We, the manufacturer,

Hebei Titans Hongsen Medical Technology Co., Ltd.  
Eastern Industrial Zone, Nangong City, Xingtai City, Hebei, China

declare in our sole responsibility that the product

Trade Name	Reference Number
Joza Nitril Handschuhe, Größe S bis XL	Joza 8002S identical to Titans N48CBL1 Size S Joza 8002M identical to Titans N48CBL1 Size M Joza 8002L identical to Titans N48CBL1 Size L Joza 8002XL identical to Titans N48CBL1 Size XL

complies with:

The **medical device directive 93/42/EEC** and applicable national regulations, being a medical device of class I according to directive 93/42/EEC, Annex IX, rule 1.

Conformity was assessed according to directive 93/42/EEC, Annex VII.

Applied product standards for medical devices:

EN 455-1:2000, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009

The **personal protective equipment regulation (EU) 2016/425** and applicable national regulations, being a personal protective equipment of category III according to regulation (EU) 2016/425, Annex I. Conformity was assessed according to Regulation (EU), Article 19, using the procedures set out in Annex V (module B) and Annex VIII (module D).

The product is identical to the personal protective equipment subject to EU Type Examination Certificate Registration No. BP 60151281 0001, Report No. 60399914 002 issued by:  
TÜV Rheinland LGA Products GmbH, Tillystraße 2, 90431 Nürnberg, Germany,  
notified body No. 0197

Production control is performed according to module D as detailed in certificate CN19/42142 issued by:

SGS FIMKO OY, P.O. Box 30 (Särkiniementie 3), 00211 Helsinki, Finland, notified body No. 0598

Applied product standards for personal protective equipment:

EN 420:2003 + A1:2009, EN ISO 374-1:2016, EN 374-2:2014, EN 374-4:2013, EN ISO 374-5:2016,  
EN 16523-1:2015

Authorised representative is:

MedNet GmbH, Borkstrasse 10, 48163 Münster, Germany

Place, Date

25.11.2020

Name, Function, Signature



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