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## MDR Zertifikat für sunaMed Nitril Handschuhe

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### sunaMed Dokumenten Nummer:

sunamed1001

### Aktuelle Version:

Auflage 1 Erstellt am: 10.9.2021

Mit Erscheinen dieser Version verlieren alle vorigen Versionen ihre Gültigkeit.

### Gültig für nachfolgende Artikelnummern:

Gr.	EAN	Art.- Nr.		Artikel
S	4260274354544	1080	100 Handschuhe S blau Nitril MDR1 noP sunaMED	100 Exam gloves S blue nitrile MDR1 noP sunaMED
M	4260274354551	1081	100 Handschuhe M blau Nitril MDR1 noP sunaMED	100 Exam gloves M blue nitrile MDR1 noP sunaMED
L	4260274354568	1082	100 Handschuhe L blau Nitril MDR1 noP sunaMED	100 Exam gloves L blue nitrile MDR1 noP sunaMED
XL	4260274354575	1083	100 Handschuhe XL blau Nitril MDR1 noP sunaMED	100 Exam gloves XL blue nitrile MDR1 noP sunaMED

### Abkürzungen:

MDR1 = MDR Klasse 1

noP = no Powder

## MDR Zertifikat

### EU Declaration of Conformity

Manufacturer: GUANGZHOU JUNDA GLOVES CO., LTD  
NO. 38 HETINGFENGWEI INDUSTRIAL ZONE, RENHE TOWN,  
BAIYUN DISTRICT, GUANGZHOU, GUANGDONG PROVINCE, CHINA

SRN: /

European Representative: CMC Medical Devices & Drugs S.L.  
C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain

SRN: ES-AR-000000293

Product Name: Medical Examination Gloves

Specifications: Nitrile

GMDN Code: 56286

UMDN Code: 11882

BASIC-UDI: 69332903JD-N902BS

Classification (MDR, Annex VIII): Class I, Rule 1.

Conformity Assessment Route: EU DECLARATION OF CONFORMITY following the Annex II + Annex III + Article 19 of MDR (EU) 2017/745.

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EU Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer.

The manufacturer is exclusively responsible for the declaration of conformity.

General applicable regulations, directives:

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Applied standards, common specification, guidance:

EN 455-1:2000, EN 455-2:2015+A2:2013, EN 455-3:2006, EN 455-4:2009, EN ISO 15223-1:2016, EN 1041:2008, EN ISO 14971:2012, EN 62366-1:2015+AC:2015, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010, ISO 188:2011, ISO 21171:2006. MDCG 2019-15.

Signature:  Cao

Name:

Position: General Manager

Place/date: China, June 10<sup>th</sup>, 2021

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## Kontakt Bezug

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**Webseite:**

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## Bestätigung

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**Dr. Klaus Huck, QM**