



**DLGS 81**  
AMBIENTE E  
SICUREZZA

## Dichiarazione di conformità prodotto e certificazione EC REP del produttore

Tutti i diritti relativi al presente documento sono strettamente riservati. Qualunque tipo di riproduzione e/o distribuzione è vietata.

# EU Declaration of Conformity

**1. Product Name:**

Disposable Powder Free Nitrile Gloves  
Product reference: CH-N001  
Color blue, size: S6, M7, L8, XL9

**2. Manufacturer:**

Name: Jiangsu Cherish Medical Technology Co., Ltd.  
Address: No. 55 Maqianan Chaoyang Road, Jiaoxi Centralized Industrial Zone, Zhenlu, Tianning,  
Changzhou City, China

**3. Statement:** This EU Declaration of Conformity is issued under the sole responsibility  
of the manufacturer: Jiangsu Cherish Medical Technology Co., Ltd.

**4. Object of the declaration:**

Disposable Powder Free Nitrile Gloves

**5. Conformity EU legislation:**

The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation  
legislation: Personal Protective Equipment Regulation (EU) 2016/425 CAT. III

**6. Standard Applied:**

The relevant EU harmonised standard used is: EN ISO 374-1:2016+A1:2018/Type B,  
EN ISO 21420:2020,  
EN ISO 374-2:2019, EN ISO 374-4:2019,  
EN ISO 374-5:2016,  
EN 16523-1:2015+A1:2018.

**7. Notified Body:**

Name: SATRATECHNOLOGY EUROPE LIMITED  
Address: Bracetown Business Park,Clonee,  
D15YN2P - REPUBLIC OF IRELAND

Identification number: 2777 - Certificate No. 2777/16240-01/E00-00  
issued on 06.04.2021



**8. Conformity Assessment Route:**

Based on the type-examination (Module B) conducted with the evaluation of test reports, technical file according  
to Personal Protective Equipment Regulation (EU) 2016/425 Annex V and based on the evaluation of test reports  
internal quality control audit reports according to EN ISO 374- 1:2016+A1:2018/Type B , EN ISO 374-5:2016  
and Personal Protective Equipment Regulation (EU)2016/425

**9. (EU) Declaration of Conformity:**

Place and Date of Issue: Changzhou city, Jiangsu, China 06.04.2021

Signature: Liu Hui

Name: Liu Hui

Position: General Manager



# EC REP CERTIFICATE



## CMC MEDICAL DEVICES & DRUGS SL NO. CMC/CE/2020/16102020.2

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized  
Representative of  
**JIANGSU CHERISH MEDICAL TECHNOLOGY CO., LTD.**  
**No 55 Maqianan Chaoyang Road, Jiaoxi Centralized Industrial Zone,**  
**Zhenglu Tianning, Changzhou City, CHINA**

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.

The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 93/42/EEC on medical devices as amended.

The products in Annex I was registered in Spanish MOH with number **RPS/2375/2020**

# CE

Issued on: 16/10/2020

Valid until: 15/10/2021

  
Authorized signatory  
CMC Medical Devices & Drugs SL

# EC REP CERTIFICATE



ANNEX I Medical Device Products



Disposable Medical Gloves

# CE