

EU Declaration of Conformity

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices
Name: Taizhou Xinkang Medical Materials Co., Ltd.

Manufacturer: Address: No.18, Wuzhou (South) Road, 225300 Taizhou, Jiangsu, People's Republic of China

SRN: CN-MF-000012941

European Representative: Name: MedPath GmbH
Address: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

SRN: DE-AR-000000087

Product Name: Patient Examination Gloves(Nitrile)

Trade Name: NitraGuard

Trade Mark : nextRESCUE

Product REF: TX1408 / NR55-HU-NGBS-002
TX1274 / NR55-HU-NGBL-002
TX1227 / NR55-HU-NSBL-001
TX1275 / NR55-HU-NGBXL-002
TX1273 / NR55-HU-NGBM-002

Product Type and Size: Size S , 290mm
Size L , 290mm
Size L , 240mm
Size XL , 290mm
Size M , 290mm

Basic UDI-DI: 69531026EGW0403ANS2T

EMDN Code: T01020204

Classification
Acc. to MDR Ax. VIII: Class I, Rule 1

Applied Common Specification/
standard: EN ISO 13485:2016/A11:2021 EN ISO 14971:2019/A11:2021 EN ISO 10993-1:2020
EN ISO 10993-5:2009 EN ISO 10993-10:2023 EN ISO 10993-12:2021
EN ISO 10993-23:2021 EN ISO 15223-1:2021 EN ISO 20417: 2021
EN 62366-1: 2015+A1:2020 EN 455-1:2020 EN 455-2:2015
EN 455-3:2015 EN 455-4:2009

Conformity Assessment Procedure: MDR Annex II + Annex III

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR), any other relevant Union legislation that provides for the issuing of an EU declaration of conformity, any CS used and in relation to which conformity is declared and other relevant regulations. All supporting documentations are retained under the premises of the manufacturer.

Signature:



Mr. Shuai Wei, PRRC

2026.7.27

Date of Issue

Taizhou, China

Place of Issue