

**EU DECLARATION OF CONFORMITY OF
MEDICAL DEVICES
AND
PERSONAL PROTECTIVE EQUIPMENT**

Manufacturer:

KRAPE ITALIA - S.r.l.
Via Jonio, 115
74121 Taranto (TA) – Italy

SRN number:

IT-MF-000040657

Product & identification:

Disposable Nitrile Gloves, Powder Free, Non-Sterile

Product code	Commercial name
066050	Disposable Nitrile Gloves, Powder Free, Non-Sterile, colour blue, Size S
066051	Disposable Nitrile Gloves, Powder Free, Non-Sterile, colour blue, Size M
066052	Disposable Nitrile Gloves, Powder Free, Non-Sterile, colour blue, Size L
066053	Disposable Nitrile Gloves, Powder Free, Non-Sterile, colour blue, Size XL
066054	Disposable Nitrile Gloves, Powder Free, Non-Sterile, colour blue, Size XS

UDI numbers:

Product code	UDI number
066050	843512541033BJ
066051	843512541034BL
066052	843512541035BN
066053	843512541036BQ
066054	843512541351C3

Model and EMDN code:

Star Nitrile // T01010202

Intended use:

Powder-free nitrile gloves are intended to be used in medical field to protect both the patient and the medical professional.

Intended purpose of the declaration:

The object of this declaration is in conformity with the Medical Device Regulation (MDR) 2017/745 (EU)

Also it is in conformity with the relevant Union Harmonisation Legislation 2016/425 (EU)

And we do hereby declare that the above mentioned product, described under the Technical Documentation, do conform to the requirements set out in European Regulation 2017/745 and 2016/425, together with the European Normative 455/1/2/3/4, EN ISO 374 – 1/2/4/5, EN 16523-1 and 21420:2020.

These medical devices have been assigned to Class I according to Annex VIII of the Regulation 2017/745, so it bears the CE mark according to Annex V. They follow the procedure relating to the EU Declaration of Conformity set out in Annex IV of Regulation (EU) 2017/745.

We declare under our sole responsibility that the products to which this declaration relates are in conformity with the requirements defined above.

Notified body

The notified body CIMAC Certifications. Via Alberto Riva Villasanta, 3 – 20145 Milan – Italy. Notified body: 0465, performed the EU type-examination and issue the EU type-examination Certificate Nr.: G-473-07162-24 del 17/01/2024

SIGNED FOR AND BEHALF OF:

Krape Italia S.r.l.
Legal Representative
Jose Santos Ruiz
Taranto. 01/03/2025

Firma

Jose Santos Ruiz
(Presidente CdA)

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