



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

Manufacturer:

KRAPE ITALIA - S.r.l.
Via Internati n° 1943-1945, n.18
31057 Silea (TV) – Italy

SRN number:

IT-MF-000040657

Product & identification:

Disposable Nitrile Gloves, Powder Free, Non-Sterile

Product code	Commercial name
040100	Disposable Vinyl Gloves, Powder Free, Non-Sterile, Size S
040101	Disposable Vinyl Gloves, Powder Free, Non-Sterile, Size M
040102	Disposable Vinyl Gloves, Powder Free, Non-Sterile, Size L
040103	Disposable Vinyl Gloves, Powder Free, Non-Sterile, Size XL

UDI numbers:

Product code	UDI number
040100	843512541037BS
040101	843512541038BU
040102	843512541039BW
040103	843512540092BT

Model and EMDN code:

Star Vinyl // T01020201

Intended use:

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

KRAPE ITALIA SRL

Via Internati n° 1943-1945 18 - SILEA (TV) CAP 31057 Tel. 335 709 9189 – mail krapeitalia@gmail.com Pec

krapeitalia@legalmial.it

Partita IVA 05435570261

Numero REA TV-443622

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 – 1/5, 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-473-07294-24 del 12/02/2024

SIGNED FOR AND BEHALF OF:

Krape Italia S.r.l.
Legal Representative
Luca Pietrobon
Silea (TV): 15/03/2025

Firma

Jose Santos Ruiz
(Presidente CdA)

KRAPE ITALIA S.R.L.

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