

# EU Declaration of Conformity

## Manufacturer:

Name: Inzek International Trading B.V.

Address: Laan van de Ram 49, 7324BW – Apeldoorn – The Netherlands

SRN: NL-MF-000018438

Registered trade mark: Biozek medical

This declaration of conformity is issued under the sole responsibility of the legal manufacturer Inzek International Trading B.V.

## Product Name and Models(s):

Product Description: Biozek Nitrile Examination gloves Seize X-Small, Small, Medium, Large and X-Large (Non Sterile) Blue and Black.

REF: GLO-101XS UDI: (0)8720844002429

REF: GLO-101S UDI: (0)8720299959606

REF: GLO-101M UDI: (0)8720299959613

REF: GLO-101L UDI: (0)8720299959620

REF: GLO-101XL UDI: (0)8720299959637

REF: GLZ-101XS UDI: (0) 8720299959682

REF: GLZ-101S UDI: (0)8720299959644

REF: GLZ-101M UDI: (0)8720299959651

RE: GLZ-101L UDI: (0)8720299959668

REF: GLZ-101XL UDI: (0)8720299959675

**Classification:** Type C

## Conformity statement:

- 1)Conformity with the relevant Union harmonisation legislation: Regulation (EU) 2016/425 PPE CAT III
- 2)References to the relevant harmonised standards used, including the date of the standard, in relation to which conformity is declared:

Standard / Clause	Title
EN ISO 21420:2020	Protective gloves — General requirements and test methods
EN ISO 374-1:2016+A1:2018	Protective gloves against dangerous chemicals and micro-organisms — Part 1: Terminology and performance requirements for chemical risks
EN ISO 374-5:2016	Protective gloves against dangerous chemicals and micro-organisms — Part 5: Terminology and performance requirements for micro-organism risks

3) Where applicable, the notified body TUV Rheinland LGA Products GmbH, , Tillystraße 2, D - 90431 Nürnberg, NB: 0197 performed the EU examination (Module B) and issued the EU type-examination certificate XXXX

4)Where applicable, the PPE is subject to the conformity assessment procedure based on internal production control plus supervised product checks at random intervals (module C2) under surveillance of the notified body: TUV Rheinland LGA Products GmbH, , Tillystraße 2, D - 90431 Nürnberg, NB: 0197.

Place, Date of Issue: Apeldoorn on 24/05/2023

Signature:

Name: M. Hamid

Position: Manager

A handwritten signature in blue ink, consisting of a vertical line on the left, a horizontal line across the middle, and a vertical line on the right, with some additional scribbles in the center.