



Document Number : INTCO-CE-DC-NBR-001

Version: A/1

## EU DECLARATION OF CONFORMITY

### Manufacturer

**Name:** Shandong Intco Medical Products Co., Ltd.

**Address:** Qiwang Road, Naoshan Industrial Park. Qingzhou, Shandong, China

Declares that the MDR described hereafter

*Product name and model:*

**Disposable Nitrile (NBR) Gloves**

**UMDNS code: 11882**

UDI-DI: (XS, S, M, L, XL, XXL)

**Blue Gloves:** 6970245756014 / 6970245756021 / 6970245756038 / 6970245756045 / 6970245756052 / 6970245756069

**White Gloves:** 6970245756410 / 6970245756427 / 6970245756434 / 6970245756441 / 6970245756458 / 6970245756465

**Black Gloves:** 6970245756519 / 6970245756526 / 6970245756533 / 6970245756540 / 6970245756557 / 6970245756564

**Violet Gloves:** 6970245756311 / 6970245756328 / 6970245756335 / 6970245756342 / 6970245756359 / 6970245756366

Meet the provisions of the Council Regulation EU 2017/745 which apply to them.

The medical device has been assigned to class I according to Annex VIII of the Regulation EU 2017/745. It bears the mark



CONFORMITY ASSESSMENT ROUTE: EU 2017/745, Annex I & VII

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

**Company:** Shandong Intco Medical Products Co., Ltd.  
**Address:** Qiwang Road, Naoshan Industrial Park. Qingzhou, Shandong, China

Shandong 2019-05-06

Place, date

5.1.2e

Plant manager

Legally binding signature, Function