

	山东英科医疗制品有限公司 Shandong Intco Medical Products Co., Ltd.	文件编号 Doc No.	INTCO-TF-NBR
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一次性 NBR 手套-技术文档 Disposable Nitrile Gloves-Technical File		页 次 Page	3/91
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INTCO-TF-NBR-01

符合性声明 **EU Declaration of Conformity**

见附件符合性声明 INTCO-CE-DC-NBR



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

Version: A/1

EU DECLARATION OF CONFORMITY

Manufacturer

Authorized Representative

Name: Shandong Intco Medical Products Co., Ltd.

Name: Lotus NL B.V.

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

Address: Koningin Julianaplein 10, le Verd, 2595AA, The Netherlands

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

Chi Yongtao Plant manager

Place, date

Legally binding signature, Function