



Document Number : INTCO-CE-DC-NBR-002

Version: A/0

EU DECLARATION OF CONFORMITY

Manufacturer

Authorized Representative

Name: Shandong Intco Medical Products Co., Ltd.
Address: Qiwang Road NO.9888, Naoshan Industrial Park, Qingzhou, Shandong, China

Name: Lotus NL B.V.
Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands

Declares that the MDR described hereafter

Product name and model:

Disposable Nitrile Exam Gloves / SYNGUARD® Nitrile Exam Gloves

EMDN code: T01020204

Model: XS /S /M /L /XL/XXL

Product Code: NGV/B/H/PEM; SNV/B/H/PE (Please refer to the attachment for more details.).

Basic UDI-DI: 697024575Nitrile7G

SRN: CN-MF-000002100

This Declaration of Conformity is issued under the sole responsibility of the manufacturer: Shandong Intco Medical Products Co., Ltd.

Conformity Assessment Route: Annex II and Annex III according to EU 2017/745.

Applicable Standard:

EN ISO 13485:2016; EN 14971:2019; EN 1041:2008; EN 15223-1:2016;

EN 455-1:2020; EN 455-2:2015; EN 455-3:2015; EN 455-4:2009;

ISO 10993-1:2018; ISO 10993-10:2010. ISO 10993-11:2017.

Meet the provisions of the Council Regulation EU 2017/745 and Annex I which apply to them,

The medical device has been assigned to Class I, based on rule 1 & rule 5 of Annex VIII

Chapter III of the Regulation EU 2017/745 MDR. It bears the mark



We agree to develop, implement and maintain a documented post-production monitoring process.

Shandong 2021-07-22

Place, date

Rick Cheng Quality Manager

Legally binding signature Function



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
	版本 Ver.	A0
一次性NBR手套-技术文档 Disposable Nitrile Gloves-Technical File	页次 Page	1/29
	日期 Date	2019/6/11



Attached: Product code (REF):

Color	Size			
	S	M	L	XL
Blue	1221	1222	1223	1224