



Document Number : INTCOAH-CE-DC-Synmax-001

Version: A/1

EU DECLARATION OF CONFORMITY

Manufacturer

Authorized Representative

Name: Anhui Intco Medical Products Co., Ltd.

Name: Lotus NL B.V.

Address: No. 6, Haitang South Road, Suixi Wuhu Modern Industrial Park, Suixi County, Huaibei City, Anhui Province

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands

Declares that the MDR described hereafter

Product name and model:

Synmax Vinyl Exam Gloves

EMDN code: T01020299

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

Product Code: See the following annex I

Basic UDI-DI: 697306977SynmaxWW

SRN:CN-MF-000002356

This Declaration of Conformity is issued under the sole responsibility of the manufacturer:
Anhui 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 455-1:2000; EN 455-2:2015; EN 455-3:2015; EN 455-4:2009;

ISO 10993-1:2018; ISO 10993-10:2010. ISO 10993-05:2009.

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.



ANNEX I Product list

Color	Product Code
Blue	SGV/B/H/PEM10013-SGV/B/H/PEM10017
	SGV/B/H/PEM15013-SGV/B/H/PEM15017
	SSV/B/H/PE10013-SSV/B/H/PE10017
	SSV/B/H/PE15013-SSV/B/H/PE15017
White	SGV/B/H/PEM10023-SGV/B/H/PEM10027
	SGV/B/H/PEM15023-SGV/B/H/PEM15027
	SSV/B/H/PE10023-SSV/B/H/PE10027
	SSV/B/H/PE15023-SSV/B/H/PE15027
Voilet	SGV/B/H/PEM10033-SGV/B/H/PEM10037
	SGV/B/H/PEM15033-SGV/B/H/PEM15037
	SSV/B/H/PE10033-SSV/B/H/PE10037
	SSV/B/H/PE15033-SSV/B/H/PE15037
Black	SGV/B/H/PEM10043-SGV/B/H/PEM10047
	SGV/B/H/PEM15043-SGV/B/H/PEM15047
	SSV/B/H/PE10043-SSV/B/H/PE10047
	SSV/B/H/PE15043-SSV/B/H/PE15047

Anhui 2021-04-16

Place , date



Quality Manager

Legally binding signature, Function

