



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

Version:A/0

EU DECLARATION OF CONFORMITY

Manufacturer

Name: Anhui Intco Medical Products
Co.,Ltd.
Address: No.6, Haitang South Road, Suixi
Wuhu Modern Industrial Park, Suixi
County, Huaibei City, Anhui Province,
China
SRN: CN-MF-000002356

Authorized Representative

Name: Lotus NL B.V.
Address: Koningin Julianaplein 10, le Verd,
2595AA, The Hague, Netherlands
SRN: NL-AR-000000121

Product name and model:

SentinaR Nitrile Exam Gloves

EMDN Code: T01020204

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

Product Code: 155360/155361/155362/155363/155364

Basic UDI-DI: 697306977NitrileFR

This declaration of conformity is issued under the sole responsibility of the manufacturer:

Anhui Intco Medical Products Co.,Ltd.

Intended use: It is mainly used for medical examination and plays the role of isolation and protection.

The conformity assessment procedure followed is Module B + Module D, in accordance with Regulation (EU) 2016/425. The medical device as specified above also complies with the conformity assessment procedure set out in Annex II and III of Regulation (EU) 2017/745.

Classification: Class I for medical device (rule I & rule 5, Annex VIII MDR), Cat III for PPE

We declare that the production of medical devices as specified above is carried out in accordance with MDR EU 2017/745 and PPE regulation EU 2016/425

MDR Harmonized Standard: EN ISO 13485:2016; EN 14971:2019; EN 20417:2021; EN 15223-1:2021; EN 455-1:2020+A2:2024; EN 455-2:2024; EN 455-3:2023; EN 455-4:2009; ISO 10993-1:2020; ISO 10993-10:2023; ISO 10993-5:2009.

PPE Harmonized Standard: EN ISO 21420:2020+A1:2024, EN ISO 374-1:2016 +A1:2018, EN 374-4:2019, EN ISO 374-5:2016

The notified body SATRA Technology Europe Ltd (Number: 2777) performed:

- EU type-examination Certificate (Module B), certificate number: 2777/14815-05/E78-01

Module D certificate

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

Anhui 2024.8.10
Place, date

Quality Manager
Legally binding signature, Function

