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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
SRN: CN-MF-000002356

Authorized Representative

Name: **Lotus NL B.V.**

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands
SRN: NL-AR-000000121

Product name and model:

Sentina® Vinyl Exam Gloves

EMDN code: T01020201

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

Product Code: 142560/142561/142562/142563/142564

Basic UDI-DI: 697306977VinylDU

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 Requlation (EU) 2017/745.

Classification: Class I for medical device(rule1& 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, EN ISO 374-1:2016 +A1:2018, EN374-4:2019, EN ISO 374-5:2016

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

- EU type-examination Certificate (Module B), certificate number: 2777/14715-04/E22-01
- Module D certificate

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

Anhui 2026.8.14

王秀娟 Quality Manager