



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-PPE-LAT

版本 Ver.

A0

EU Declaration of Conformity

We declare that the following product is carried out in accordance with Regulation (EU) 2016/425.

1. PPE: Disposable Latex Gloves/ SYNGUARD® Latex Exam Gloves

Glove sizes available: S, M, L, XL (7, 8, 9, 10)

Product code: LGV/B/H/PE(10024-10027); LGV/B/H/PE(10024P-10027P) ;

LGV/B/H/PE(10F24-10F27); LGV/B/H/PE(10F24P-10F27P) ;

LGV/B/H/PE(10P24-10P27); LGV/B/H/PE(10P24P-10P27P);

SLV/B/H/PE(10024-10027) ; SLV/B/H/PE(10024P-10027P)

2. Manufacturer Name: Shandong Intco Medical Products Co., Ltd.

Address: No.9888,Qiwang Road, Naoshan Industrial Park. Qingzhou, Shandong, China

3. This declaration of conformity is issued under the sole responsibility of the manufacturer: Shandong Intco Medical Products Co., Ltd.

4. Object of the declaration: Disposable Latex Gloves/ SYNGUARD® Latex Exam Gloves

5. The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation legislation: Regulation (EU)2016/425.

6. References to the relevant harmonised standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared: EN ISO 21420:2020, EN ISO 374-1:2016 +A1:2018, EN374-2:2019, EN ISO 374-5:2016.

7. The notified body SATRA Technology Europe Ltd (Number: 2777) performed the EU type-examination (Module B) and issued the EU type-examination certificate.

8. The PPE is subject to the conformity assessment procedure Module C2 under surveillance of the notified body : SATRA Technology (Number: 2777),

Adress: Bracetown Business Park Clonee, D15 YN2P, Ireland.

Signed for and on behalf of: Shandong Intco Medical Products Co., Ltd.

签名 Singnature 程军建

职位 Position Quality Manager

日期 Date 2-June-2021