

Declaration of Conformity

This declaration is issued under the sole responsibility of the manufacturer

Object of the declaration:

Product Disposable nitrile gloves. 100 st

Model/type factory ZHPFN02

Model/type Action M - 2562713

L - 2565719

EAN - M 8715342042619

EAN - L 8715342042626

Product photograph:



Medium:



Large:

Manufacturer:

Authorised Representative

Zhonghong Pulin Medical Products Co.,Ltd.

West Industrial Park, Luannan County, Tangshan City, 063500, Hebei, China

Tel: +86 315-4167275 4167652 4149201

Lotus NL B.V.

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

The object of the declaration described above is in conformity with the relevant Union harmonization legislation:

Meets the conditions laid down in the following harmonized standards:

Medical Device Directive 93/42/EEC

- Risk class: Class I based on rule 1 (Annex IX of the MDD 93/42/EEC)

- Test standard: EN 374, EN 16523, EN 21420, EN 455

Conformity is shown by compliance with the applicable requirements of the following documents:

Testing lab	Test report no.
SATRA Technology Service (Dongguan) Ltd.	CHM0309851/2110/LC/A
SATRA Technology Service (Dongguan) Ltd.	CHM0314155/2122/LC
SATRA Technology Service (Dongguan) Ltd.	CHT0309328/2109
TÜV SÜD PSB Singapore	7191240823-EEC20/03-LDY_ CR1
TÜV SÜD PSB Singapore	7191240823-EEC20/02-LDY_ CR1

The notified body: SATRA Technology Europe Limited.
Bracetown Business Park Clonee Dublin 15 D15 YN2P.
Republic of Ireland.
Nobo nr.: 2777

Signed for and on behalf of: Zhonghong Pulin Medical Products Co.,Ltd.

Place of issue: Tang Shan
Date of issue: 15-5-2023
Name: Zhao En You
Position: General Manager

Signature:

