EU DECLARATION OF CONFORMITY

[redacted]

Identification of the Legal Manufacturer & Address	[redacted]
European Authorized Representative	EC REP :Lotus NL B.V. : Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands [redacted]
Basic UDI-DI	[redacted]
Product & Identification	: **Disposable Nitrile Examination Gloves, Powder Free**
Intended purpose of the product:	:The Disposable Nitrile Patient Examination Gloves is a disposable Product intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.
GMDN code and product:	**: 56286 Nitrile examination/treatment glove, non-powdered, non-sterile**
SRN Number:	[redacted]
Risk Classification:	: Class 1, Non-sterile, no measuring function and not surgical instrument

We hereby declare that the above mentioned devices comply with the European Medical Device Regulations (EU) MDR 2017/745. The EU declaration of conformity is issued under the sole responsibility of the manufacturer.

Conformity Assessment Procedure	: Article 52(7) and : Annex VIII, 4.1 Rule 1, Non-invasive device, and/or : 5.1 intended for transient use, Rule 5 of invasive device.
Conformity Route	: Self-Declaration
Relevant Harmonized Standards:	: EN ISO13485:2016 : EN 455-1: 2000, EN455-2:2015, EN455-3:2015
EN 455 Standard Test Report	1. [redacted] 2. 3. 4. 5.
Quality System Certificate	: Certificate No: Q5 062837 0012 Rev. 02 : Certificate Body: TUV SUD Product Service GmbH : Issued Date: 12 Nov 2019 Valid Date: 31 Jul 2022
Identification of the person authorized to sign on behalf of the Legal Manufacturer:	:Signed by: [redacted] :Print Name: [redacted] :Title: Quality Director :Place: [redacted] China :Date: 23 Feb 2021