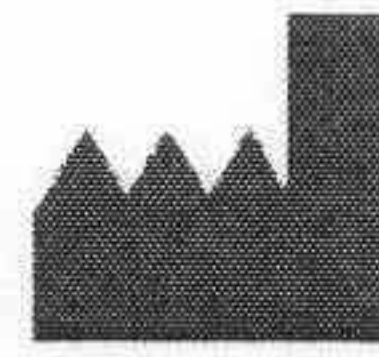


EU DECLARATION OF CONFORMITY

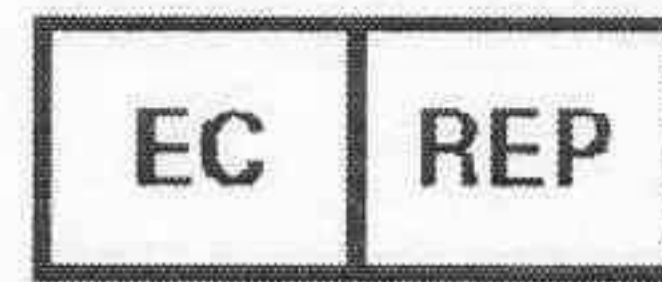
Doc No.: D-MDR-09/08-A01

**Identification of the Legal
Manufacturer & Address**



: Zibo Blue Sail Innovation Co., Ltd
: No. 21 Qingtian Road, Qilu Chemical Industrial Park,
Zibo, Shandong 255414 China

**European Authorized
Representative**



: Lotus NL B.V.
: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague,
Netherlands
: Email: peter@loutsnl.com

Product & Identification

: **Disposable Nitrile Examination Gloves, Powder Free**

**Intended purpose of the
product:**

The Disposable Nitrile 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**

EMDN code:

: **T01020204 GUANTI NON CHIRURGICI IN NITRILE
EXAMINATION / TREATMENT GLOVES, NITRILE**

Manufacturer SRN Number:

: CN-MF-000023103

REP SRN Number:

: NL-AR-000000121

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: 2020, EN455-2:2015, EN455-3:2015, EN455-4:2009

EN 455 Standard Test Report

7191273970-EEC22-01-WBH
7191273970-EEC22-02-WBH
7191273970-EEC22-03-WBH
7191273970-EEC22-04-WBH
7191294702-EEC22-WBH

Quality System Certificate

: Report No. BJ22092401
: Certificate Body: TUV SUD Product Service GmbH
: Issued Date: 04 Aug 2022 Valid Date: 31 Jul 2025

**Identification of the person
authorized to sign on behalf of
the Legal Manufacturer:**

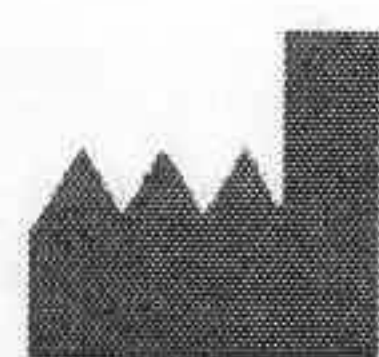
: Signed by:

: Print Name: Robin Liu
: Title: Quality Director
: Place: Zibo, Shandong, China
: Date: 25 Nov 2022

EU DECLARATION OF CONFORMITY

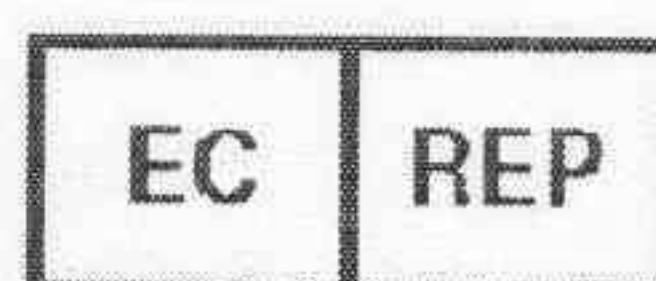
Doc No.: D-MDR-09/08-A01

**Identification of the Legal
Manufacturer & Address**



: Zibo Blue Sail Innovation Co., Ltd
: No. 21 Qingtian Road, Qilu Chemical Industrial Park,
Zibo, Shandong 255414 China

**European Authorized
Representative**



: Lotus NL B.V.
: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague,
Netherlands
: Email: peter@loutsnl.com

Product & Identification

: **Disposable Long Cuff Nitrile Examination Gloves, Powder Free**

**Intended purpose of the
product:**

The Disposable Nitrile 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**

EMDN code:

: **T01020204 GUANTI NON CHIRURGICI IN NITRILE
EXAMINATION / TREATMENT GLOVES, NITRILE**

Manufacturer SRN Number:

: CN-MF-000023103

REP SRN Number:

: NL-AR-000000121

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: 2020+A1:2022, EN455-2:2015, EN455-3:2015, EN455-4:2009

EN 455 Standard Test Report

7191290097-EEC22-WBH_CR1

Quality System Certificate

: Certificate No.Q5 062837 0012 Rev.04
: Certificate Body: TUV SUD Product Service GmbH
: Issued Date: 04 Aug 2022 Valid Date: 31 Jul 2025

**Identification of the person
authorized to sign on behalf of
the Legal Manufacturer:**

: Signed by:

: Print Name: Robin Liu
: Title: Quality Director
: Place: Zibo, Shandong, China
: Date: 23 Sep 2022