

Kuśnie, 03.01.2025

## EU DECLARATION OF CONFORMITY

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

**Authorized representative :**  
**Lotus NL B.V.**  
**Koningin Julianaplein 10, 1e Verd,**  
**2595AA, The Hague, Netherlands**

declares that the goods described below are classified as short term wear clothing (disposable clothing) and are allowed to come into contact with any type of food in a short period of time

**Product code:**

### DIAMANTE/VB

<b>Name and type</b>	Disposable nitrile examination gloves DIAMANTE, powder free
<b>Size</b>	S, M, L, XL
<b>Color</b>	violet-blue (vb)
<b>Category III</b>	protection against substances and mixtures hazardous to health
<b>complies with :</b>	

- the provisions of the EU Regulation 2016/425, module C2 EU – CE no. 2777/24291-01/E00-00
- Commission Regulation (EC) No. 10/2011 of January 14, 2011 and Regulation (EC) of the European Parliament and of the Council No. 1935/2004 of October 27, 2004 "on plastic materials and articles intended to come into contact with food " and has the required migration test reports
- EN standard EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-4:2019, EN ISO 374-5:2016



EN ISO 374-5:2016



EN ISO 374-1 / Typ B



**GLOBAL FOOD HYGIENE**  
**D. Urbański Spółka Komandytowa**  
98-200 Sieradz, Kuśnie 41D  
NIP 8272307627, Regon 360982808

Kuśnie, 03.01.2025

**USE IN THE FOOD INDUSTRY IN ACCORDANCE WITH THE COMMISSION REGULATION (EC) No 10/2011 OF 14.01.2011; WITH REGULATION (EC) OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL NO 1935/2004 ON PLASTIC MATERIALS AND ARTICLES INTENDED TO CONTACT WITH FOOD**

**PRODUCT CODE : DIAMANTE/VB**

**NAME AND TYPE:** Disposable nitrile examination gloves DIAMANTE, powder free / violet-blue

Through the declaration of conformity, the manufacturer guarantees that the raw materials used for the above-mentioned products are always of the same type. In addition, the manufacturer ensures that GLOBAL FOOD HYGIENE will be informed of any changes to raw materials and methods in good time before these changes come into force, to enable the appropriate tests to be carried out in accordance with Regulations 10/2011 and 1935/2004.

**MIGRATION TEST:** A complete migration test was carried out in accordance with Regulations (EU) No. 10/2011 (Annex III and V) and 1935/2004. Tested according to EN 1186-1:2002, EN 1186-9:2002, EN 1186-2: 2002.

**Test conditions:** 2 hours at 70 degrees Celsius

**TEST SIMULANTS:** ETHANOL 10%, ACETIC ACID 3%, Olive Oil

**WE GUARANTEE THAT THE ABOVE PRODUCTS MEET THE REQUIREMENTS OF THE REGULATIONS, PROVIDED THAT THE PRODUCTS ARE USED AS IT IS INTENDED, FOR ALL KINDS OF FOOD AT TEMPERATURE UP TO +70 C. FOR 2 HOURS**

**Signed on behalf of the Manufacturer**

Importer :  
**GLOBAL FOOD HYGIENE**  
**D. URBAŃSKI SPÓŁKA KOMANDYTOWA**  
**Kuśnie 41D**  
**98-200 Sieradz**

**This declaration of conformity is issued under the sole responsibility of the Manufacturer.**

**GLOBAL FOOD HYGIENE**  
D. Urbanski Spółka Komandytowa  
98-200 Sieradz, Kuśnie 41D  
NIP 827 230 76 27, Regon 360982808

Kuśnie, 03.01.2025

## **EU DECLARATION OF CONFORMITY**

**In accordance with the regulation on medical devices (EU) 2017/745**

**Manufacturer:**

**Blue Sail Medical Co., Ltd**

**No. 21Qingtian Road, Qilu Chemical Industrial Park,**

**Zibo, Shandong 255414 China**

**REP SRN: NL-AP-000000121**

declares under his sole responsibility that article "Nitrile examination gloves DIAMANTE, powder free / violet-blue"

Basic UDI-DI 69332655EM01021562864B

Comply with the provisions of Regulation (EU) 2017/745 and with the standards:

EN ISO 13485:2016

EN 455-1: 2020

EN 455-2: 2015

EN 455-3: 2015

EN 455-4: 2009

This product is a class I medical device according to the classification in accordance with Annex VIII.

**Signed on behalf of the Manufacturer**

Importer :

**GLOBAL FOOD HYGIENE**

**D. URBAŃSKI SPÓŁKA KOMANDYTOWA**

**Kuśnie 41D**

**98-200 Sieradz**

This declaration of conformity is issued under the sole responsibility of the Manufacturer.

**GLOBAL FOOD HYGIENE**  
D. Urbański Spółka Komandytowa  
98-200 Sieradz, Kuśnie 41D  
NIP 8272607627, Regon 360982808