



**P.T. ARISTA LATINDO**

PERSONAL CARE PRODUCTS

OFFICE : JL. K.H. MOH. MANSYUR 128 JAKARTA 11210 - INDONESIA. MAILING ADDRESS : P.O. BOX 4129 JKT. 11041 - INDONESIA  
TELEPHONE : (62-21) 874-0982. FAX : (62-21) 874-0979. E-MAIL : contact@aristagloves.com

## **EC DECLARATION OF CONFORMITY**

According to the requirements of MDR Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83 / EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223 / 2009 and repealing Council Directives 90/385 / EEC and 93/42 / EEC

We,

**PT. ARISTA LATINDO**  
JL. K. H. MOH. MANSYUR #128  
JAKARTA 11210, INDONESIA

declare under our sole responsibility that the following non-sterile product under Class I meets the provisions of the MDR Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83 / EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223 / 2009 and repealing Council Directives 90/385 / EEC and 93/42 / EEC, concerning medical devices which apply to them :

Product description : **Home Sweet Home Expert Disposable Gloves Nitrile 100 pcs**  
Product Code/Name : 100000022 – size S ; 100000023 – size M ; 100000024 – size ; 100000025 – size XL  
Invoice # : INV. 388/AL-XII/2021  
Date : 13 December 2021

The product is classified as medical device class I according to Annex VIII, Rule I of the Regulation (EU) 2017/745  
Conformity assessment procedure: Annexes II and III of the Regulation. Complies with European harmonized standards: EN 455-1:2000, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009."

The product also complies with the Regulation of the European Parliament and of the Council ( EU ) 2016/425 of 9 March 2016 on personal protective equipment and the repeal of council directive 89/686/EEC

The product meets the standards :

EN ISO 374-5: 2016 ( PL-EN ISO 374-5: 2017-02 ) ; EN 420: 2003 + A1: 2009 ( PN-EN 420 + A1: 2012 )

The product was subject to a type conformity assessment procedure based on internal production control and supervised product checks at random intervals ( module C2 ) under the supervision of Satra Technology Europe LTD ( Notified Body number 2777 )

Notified Body : Satra Technology Europe LTD, number : 2777, EU-type examination (module B) , certificate number: 2777 / 13656-02 / E-00-00

PT Arista Latindo has a certified quality management system, in accordance with the requirements of the standards: ISO 9001:2015 (certificate number 62204/A/0001/UK/En) and ISO 13485:2016 (certificate number 62204/C/0001/UK/En) issued by United Registrar of Systems.

The authorized representative within the the EU who has been empowered to enter into commitments on our behalf is :

MS POLAND Sp. Z o.o.  
30-529 Krakow  
Ul. Jozefinska 2  
POLAND

**Linga Sumarta, QA Manager**

Date : 17 March 2022

