

## DECLARATION OF CONFORMITY

(Regulation EU 2016/425)

We, the company under the name **KARABINIS MEDICAL SOCIETE ANONYME MANUFACTURE – SALE OF MEDICAL AND TECHNOLOGICAL PRODUCTS AND PROVIDING SERVICES** and the distinctive title **KARABINIS MEDICAL S.A.** , having its registered offices in Peania Attica, 151 Lavriou Av., under its sole responsibility as manufacturer, declare that the below products :

### **HYGEIA CARE – DISPOSABLE LATEX GLOVES POWDERED – NON STERILE**

1. Belong to category 1 – for minimal risk
2. Are in conformity with:
  - Regulation PPE (EC) 425/2016
  - European Standard EN 420:2003 +A1:2009
3. The above PPE that bear the CE mark are also in compliance with the requirements set in Annex IV (Module A) of the Regulation EU 425/2016.
4. The PPE is subject to the conformity assessment procedure: INTERNAL PRODUCTION CONTROL (Annex IV (Module A) of the Regulation EU 425/2016).
5. This declaration is under the sole responsibility of the above manufacturer.

Peania: 06/03/2020

The document herein is undersigned for and on behalf of Karabinis Medical S.A.

Name: Konstantinos Katsikavelis  
Position: Quality Assurance Manager  
Signature:

