

EU Declaration of Conformity

1. Product: **HY018-01 & HY018-02**

2. Name and address of the manufacturer:

**Jiangsu Huayuan Medical Technology Co., Ltd.
No.36 Nanzhuang Road, East New District of Dongtai City, 224249 Jiangsu China**

3. This declaration of conformity is issued under the sole responsibility of the manufacturer.

4. Object of the declaration: **Five finger disposable Powdered vinyl Gloves
Five finger disposable Powder free vinyl Gloves
(XS(6), S(7), M(8), L(9), XL(10))**

5. The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation legislation : **Regulation (EU) 2016/4255)**

6. References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared:

EN 420:2003+A1:2009	Section A-Size and dexterity & Section B-Innocuousness Tests
EN 16523-1:2015	Part 1: Permeation by liquid chemical under conditions of continuous contact
EN 374-1:2016	Part 1: Terminology and performance requirements for chemical risks.
EN374-2:2014	7.2 Air leak test & 7.3 Water leak test
EN 374-4:2013	Part 4: Determination of resistance to degradation by chemicals

7. Where applicable, the notified body SATRA Technology Europe 2777 performed the EU examination (Module B) and issued the EU type- examination certificate (Reference to that certificate)

Signed for and on behalf of the above named manufacturer:

Place and date of issue: **China On August 30, 2018**

Name:

Signature:

