

# *Declaration of Conformity*

**Manufacturer :**

Han Chang Medic

79-35, Jangsan 2-gil, Susin-myeon, Dongnam, Cheonan-si,  
Chungcheongnam-do, Republic of Korea



CMC MEDICAL DEVICE & DRUGS, S.I

C/ Horacio Lengo n18 C.P 29006 Málaga-Spain

**Product name:** HAN.CHANG I-SWAB, HAN.CHANG UTM

**Classification:**

HAN.CHANG I-SWAB : Class I by Rule 1 of Annex IX, MDD 93/42/EEC

HAN.CHANG UTM : Others(Annex II of the IVD Directive 98/79/EC)

**Conformity Assessment Route :**

Annex VII - MDD 93/42/EEC, Annex III - IVD Directive 98/79/EC

**Applied Standard(s) :**

ISO 9001: 2015, EN ISO14971:2012, EN ISO13485:2016, EN ISO18113-1:2011, EN ISO18113-2:2011,  
EN ISO23640:2015, ISO14644-1:2015, ISO 14644-2:2015,  
EN ISO17511:2003, EN 13612:2002, EN ISO 15223-1:2016

We hereby declare that the device described below, both in its basic design and construction and in the version marked by us, conforms to the relevant safety and health related requirements of the appropriate EU directives.

This declaration shall cease to be valid if modifications are made to the device without our approval.



Date: May 21. 2020

Representative of Han Chang Medic