

EC Declaration of Conformity

Manufacturer:

Bengbu Han Yu Technology Limited
Technology and Innovation Industrial Park,
Huaishang district, Bengbu City, Anhui
Province, China

whose single Authorized Representative:

CMC MEDICAL DEVICES & DRUGS S.L
C/Horacio Lengo N° 18
CP 29006, Málaga-Spain
www.cmcmedicaldevices.com

We, the manufacturer, herewith declare that the products

Surgical Mask

Models: HYSM021

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex of the Directive 93/42/EEC. It bears the mark



The product concerned has been designed and manufactured under a quality management system according to Annex VII of Directive 93/42/EEC.

Standard Applied:

EN ISO 14971:2012	EN ISO 15223-1:2016	EN 1041:2008
EN ISO 14683: 2019	EN ISO 10993-1:2018	EN ISO 10993-5:2009
EN ISO 10993-10:2010	EN ISO 13485:2016	93/42/EEC
MEDDEV 2.7.1 rev.4.0		

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Bengbu Han Yu Technology Limited

Address: Technology and Innovation Industrial Park, Huaishang district, Bengbu City, Anhui Province, China

Valid Date From: 2020/5/20

Valid Date Until:2021/5/19

May 20th, 2020

Place, date

GM

A handwritten signature in black ink, appearing to be '王怀礼' (Wang Huaili).

Legally binding signature, Function