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CERTIFICATE

Certificate Number **UCN** : **802776205200**
Job : J29951
Date of Issue : *2020-03-23*
Certificate valid up to : *2024-03-22*

Brand Name : *Huibo*
Type : *Medical Surgical Mask*
Model N : *HB-01*

Manufacturer : Henan Huibo Medical Co., Ltd.
Address : Weishi Road Central, Nanyang New Energy Economic and Technological Development Zone, Nanyang City, Henan Province 473000, China

Standard Used : EN 14683:2005, EN ISO 10993-1:2009+AC:2010

Conclusion :
After inspection of the technical documentation issued by the customer, and in his request, we express our opinion that the product meets the technical requirement of the following directives and standards:
93/42/EEC Medical devices (MDD)

This opinion is only valid for the directive, the equipment and configuration described, in conjunction with the test data detailed above and with compliance with all applicable legal requirement for the product .
The following manufacturer documents was inspected:

Presence of Declaration of conformity template	✔ OK
Presence of test report using standards as indicated in the declaration of conformity Test report reference : BET20200213012MDD	✔ OK
Presence of CE symbol in the product label.	✔ OK
Presence of instruction manual	✔ OK
Use of valid Harmonized standard in the declaration of conformity	✔ OK
Presence of product description in the technical construction file	✔ OK

Check the authenticity of this certificate and related information before use in the web site www.celab.com introducing the UCN number in the 'Check document authenticity' area. You will see copy of this certificate and regulation on certificate use. This document is released only for scope allowed by laws- Do not use this document without full understanding of regulation.

Massimiliano Bertoldi
General Manager – CELAB
www.celab.com

EC Declaration of Conformity

We,

Henan Huibo Medical Co., Ltd.

Weishi Road Central, Nanyang New Energy Economic and Technological Development Zone, Nanyang City, Henan Province 473000

Product: Medical Face Masks

Type: HB-01

Test report No.: BET20200213012MDD

to which this declaration relates is in compliance with the European Community (MDD) Directive 93/42/EEC, and comply with the standards listed below:

MDD

EN 14683:2005 Surgical masks - Requirements and test methods

EN ISO 10993-1:2009+AC:2010 Biological evaluation of medical devices –

Part 1: Evaluation and testing within a risk management process

Signature: _____

(Manager)

Date of issue: _____