

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 98/79/EC CONCERNING MEDICAL DEVICES

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MANUFACTURER:

Hubei Meibao Biotechnology Co, Ltd
No. 5 Hongfu Road, Shayang Economic Development
Zone, 448200, Jingmen City, China
Human Chronic Gonadotropin Colloidal Gold Test/hCG
Pregnancy Test
(strip, cassette, midstream)
Test ciążowy hCG
(paskowy, strumieniowy, płytkowy)

PRODUCT:

CLASSIFICATION - ANNEX II:

Self-testing, HS code: 3002150090

CONFORMITY ASSESSMENT ROUTE:

IVDD 98/79/EC Annex IV.3

WE, THE MANUFACTURER, HERE WITH DECLARE THAT THE STATED MEDICAL DEVICE
MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 98/79/EC
CONCERNING MEDICAL DEVICES;

ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.
WE AS THE MANUFACTURER ARE EXCLUSIVELY RESPONSIBLE FOR THE DOC.

STANDARDS APPLIED:

EN ISO 14971:2012
EN ISO 13485:2016
EN ISO 18113-4:2011
EN ISO 15223:2016

NOTIFIED BODY:

TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER

CE 0123

(EC) CERTIFICATE(S):

V1 084924 0002 Rev. 01,
valid until 2023-10-10

EC REP

EUROPEAN REPRESENTATIVE:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany
Tel. +49 40 2513175, Fax: +49 40 255726

START OF CE-MARKING:

2014-10. valid until 2023-10-10

PLACE, DATE OF DECLARATION:

JINGMEN, 2022-06-28

SIGNATURE:

Enliang Li

NAME: MR. ENLIANG LI

POSITION: GENERAL MANAGER

