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DECLARATION OF CONFORMITY

MANUFACTURER: ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.
4th Floor,D-1# Zone, Pearl Industrial Park, 106 Innovation Avenue,
High-Tech Development Zone , 230088 Hefei, Anhui, People's
Republic of China

EUROPEAN REPRESENTATIVE: Luxus Lebenswelt GmbH
Kochstr.1,47877,Willich,Germany

PRODUCT: Fecal Occult Blood & Transferrin Test (Colloidal Gold)

Models: STRIP, CASSETTE

CLASSIFICATION: SELF-TESTING

EDMA CODE: 11 70 03 90

CONFORMITY ASSESSMENT ROUTE: ANNEX IV EXCLUDING (4,6)

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

STANDARDS APPLIED: EN ISO 13485:2016
EN ISO 18113-1:2011, EN ISO 18113-4:2011, EN 13612:
2002/AC:2002, EN ISO 23640:2015, EN 13641: 2002, EN ISO
15223-1: 2016, EN 13975:2003, EN 13532:2002, EN ISO
14971:2012.

NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR.65,80339 MUNCHEN,GERMANY

(EN) CERTIFICATE(S): V1 003706 0002 Rev.01

START OF CE-MARKING: 2022-02-17

PLACE, DATE OF ISSUE: HEFEI, 2023-03-01



SIGNATURE: CHEN FENGLING *chenfengling*
GENERAL MANAGER

EC Declaration of Conformity

D00-FOB+TF(C/1)

