CE

Declaration of Conformity

According to Art. 17 of Regulation 2017/746 (EU) on in vitro diagnostic medical devices

Manufacturer: HUNAN EHOME HEALTH TECHNOLOGY COMPANY LIMITED
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SRN: ES-AR-000001202

Product: Kit for Sample Processing for Hematology Analysis
Model: YH-HC200, YH-HC201
Basic UDI-DI: 697567949EHBT50WY

Intended Use: TThe disposable capillary blood collecting tube is used to collect and store human peripheral blood; the hemolytic agent for CBC analysis is used to damage red blood cells, dissolve hemoglobin, and maintain the morphology of the cells to be analyzed prior to the CBC analysis; when needed, differential cell count is conducted following the staining of white blood cells, or differential cell count and quantitative hemoglobin test are conducted directly; the diluent for CBC analysis is used to dilute the whole blood sample to be tested, in conjunction with a blood analyzer or a reagent to test the substance to be tested. Clinically, the sample is diluted to prepare a cell suspension prior to the CBC analysis; the blood cell counting plate is used clinically to count the formed elements in blood and body fluid samples.

Classification: Class A, according to Rule 5 of IVDR Annex VIII

Conformity Assessment Route: Annex IX, IVDR (EU) 2017/746

We, manufacturer, herewith declare under our sole responsibility that the above-mentioned product meets the provisions of the following EC Council Directives and Standards. All supporting documentation is retained under the premises of the manufacturer.

List of Directive and Standard Applied:

EN ISO 14971:2019+A11:2021	EN ISO 13485:2016+A11:2021	ISO 15223-1:2021
ISO 18113-1:2022	ISO 18113-2:2022	EN 13640:2002
EN 13641:2002	EN 13612:2002	EN ISO 23640:2015

Signed this Day/1 of

Month/11 of Year/2024,

Place (Changsha Hunan), China

(Place and Date of Issue)

(Signature and Position)

Signed for and on behalf of the Manufacturer