



EC DECLARATION OF CONFORMITY

According to Regulation (EU) 2017/746

Manufacturer Jiangsu Konsung Bio-Medical Science And Technology Co., Ltd.
Address NO.8, Shengchang West Road, Danyang Development Zone,
 Jiangsu Province, 212300, P.R. China

In vitro diagnostic device(s) **Product Name:** Hemoglobin Microcuvette (Spectrophotometry)
Model: HB-01
Specification: 25 Microcuvettes /bottle,
 50 Microcuvettes /bottle,
 4*50 Microcuvettes /bottle

IVDR Classification: Class A
EDMA: 12-90-01-80-00
Basic UDI-DI: 693482255800SBC

This declaration of conformity is issued under the sole responsibility of the manufacturer that the above product(s) meet(s) the provisions of Regulation (EU) 2017/746.

The following (harmonized) standards have been applied

EN ISO 13485:2016 EN ISO 14971:2019 EN ISO 15223-1:2021
EN ISO 18113-1: 2011 EN ISO 18113-2:2011

The conformity with the requirements of the regulation has been assessed following the procedure(s) outlined in the following annexes of the regulation: Annex II and III.

Notified Body (if consulted) Not applicable

Technical documentation demonstrating compliance is kept by the manufacturer and can be made available by the authorized representative in Europe:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

PLACE, DATE OF DECLARATION:

SIGNATURE:

Jiang Su

2023.09.06

NAME: Wu Yujia

POSITION: GENERAL MANAGER

