

# DECLARATION OF CONFORMITY

**MANUFACTURER** Qingdao Hightop Biotech Co., Ltd.  
No.369 Hedong Road, Hi-tech Industrial Development Zone,  
Qingdao, Shandong, 266112, China

**EUROPEAN REPRESENTATIVE** MedNet EC-REP GmbH  
Borkstrasse 10 · 48163 Muenster · Germany

**PRODUCT** **Urinalysis Reagent Strips (Dry Chemical Method)**  
--- Analyte : Ascorbic Acid, Leukocytes, Glucose, Microalbuminuria,  
Bilirubin, pH, Blood, Specific Gravity, Ketone, Protein, Nitrite, Urobilinogen,  
Creatinine and Calcium

**CLASSIFICATION** Others

**CONFORMITY ASSESSMENT ROUTE** IVDD 98/79/EC Annex III (Excluding 6)

WE, THE MANUFACTURER, IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY. WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC. ALL SUPPORTING DOCUMENTATIONS ARE RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

**STANDARDS APPLIED** 98/79/EC, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612: 2002, EN ISO 23640:2015, EN 13641: 2002, EN ISO 15223-1: 2021, EN 13975:2003, ISO 14971:2019, EN ISO 13485: 2016, EN ISO 17511: 2021, EN 62366-1:2015.

**PLACE, DATE OF ISSUE** Qingdao, 2022-04-19

**SIGNATURE**

  
  
Mr. Frank Yang  
General Manager

CE

# HIGHTOP

QINGDAO HIGHTOP BIOTECH CO.,LTD.

## Declaration of Conformity (DOC) Corrigendum

Product name: Urinalysis Reagent Strips (Dry Chemical Method)

REF: /

Class: Others not included in IVDD 98/79/EC Annex II

Date of the DOC: 2022-04-19

Classification according to IVDR: Class B

This corrigendum intends to correct the following information in DoC(s) of the above listed product(s).

*Add Product Specimen: Human Urine*

*Update the MANUFACTURER address to 'No.369 Hedong Road, Hi-tech Industrial Development Zone, 266112 Qingdao, Shandong, PEOPLE'S REPUBLIC OF CHINA'.*

According to Regulation (EU) 2017/746 (IVDR), for legacy devices according to Art. 110 (3), amended by Regulation (EU) 2022/112, Art. 1, no changes to DOCs signed prior to May 26, 2022 can be performed. In case of the above described non-significant change(s) (as defined in MDCG 2022-6), the existing DOC(s) is (are) still valid and this Corrigendum will be attached to the originally signed DOC(s). The DOC(s) will be updated upon transition to IVDR.

Qingdao, 2025-01-21.....

Place/Date

.....  
legally binding signature

Frank Yang ..... General Manager  
Name and function

