

# Appendix H Declaration of Conformity\_1....

## CE EC Declaration of Conformity CE

Manufacturer: Changchun Wancheng Bio Electron Co., Ltd.  
Add: No. 2236, Tianwei Road, Beihu Economic Development Zone, Changchun City, Jilin Province, China.

Whose Single Authorized EU-Representative: Riomavix S.L.  
Add.: Calle de Almansa 55, 1D, Madrid 28039 Spain  
E-mail: leis@riomavix.com  
Tel.: +34 658 396 230  
(SRN: ES-AR-000001202)

Product Name: Reagent strips for Urinalysis

Classification : **Others of ANNEX II of IVDD**

Conformity Assessment Route: **Annex III**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

General applicable directives:  
In Vitro Diagnostic Medical Devices DIRECTIVE 98/79/EC

Harmonized standards:  
EN ISO 13485:2016, EN ISO 15223-1:2016, EN ISO 14971:2019, EN 13641: 2002,  
EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612: 2002, EN ISO 23640:2015

Signature:   
Name:   
Title: General manager  
Place/Date: China, May.20, 2022



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