



## Declaration of Conformity Certificate



**Manufacturer:** Atlas Link Technology Co., Ltd.

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Tel: 86-10-8890 9113 Fax: 86-10-8890 9115  
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**Products:** Helicobacter Pylori (H.Pylori) Antigen Test (Colloidal Gold)

**Catalog No.:** HP442, HP443

**Classification:** Other IVD Test Device

**Conformity Assessment Route:** Annex III Applied (IVD 98/79/EC)

**Declaration:** We herewith declare that the above mentioned products meet the Annex III provisions of the Council Directive 98/79/EC for In Vitro diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer.

**Standard Applied:** EN ISO13485:2016, EN ISO14971:2012, EN ISO 18113- 1:2011, EN ISO 18113-2:2011, EN 13612:2002, EN 13641:2002, EN ISO 15223-1:2016, EN ISO 15223-2: 2010 EN ISO 23640:2015

**Place, Date of Issue:** Beijing, P.R. China, Oct 09, 2020



**General Manager:**  
Chen Jianjiang