

One Step hCG Urine Pregnancy Test Technical File (II)	Document No	Version	Page
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II Declaration of Conformity

- Manufacturer:** Atlas Link Technology Co., Ltd.
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- European Representative:** MT Promedt Consulting GmbH.
Altenhofstr. 80
66386 St. Ingbert
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E-mail: ear@mt-procons.com
- Product:** One Step hCG Urine Pregnancy Test
(Strip/Cassette/Midstream)
- Classification:** Self-testing / IVDD Annex IV. section 3
- Conformity Assessment Route:** Annex IV (excluding 4 and 6)
- Declaration of conformity:** We herewith declare that the above mentioned products meet the provisions of EC Council Directives and Standards for Medical Devices. All supporting documentations is retained under the premises of Atlas Link (Beijing) Technology Co., Ltd.
- General applicable directives:** EN18113-1 : 2009, EN18113-4 : 2011,
EN ISO15223-1 : 2016 , ISO 15223-2:2010 ;
EN13532:2002, EN13612:2002,
EN ISO 23640:2015, EN ISO14971:2012 ,
EN ISO13485 : 2016

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Notified Body: TÜV Product Service GMBH NO. 0123
Ridlerstraße 65, 80339 München

EC Certificate: No.V1 057995 0009 Rev. 02
(Expiry date of the Certificate :2024-05-26)

Start of CE-Marking: May 12th,2006 LOT: Q05126M11

Place, Date of Issue: Beijing, May 12th, 2021

General Manager: Chen Jianjiang

