



Declaration of Conformity



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Altenhofstrasse 80, 66386 St. Ingbert, Germany
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Product:

HCG 114-1 TESTA MED SCHWANGERSCHAFTSTEST 1 ST (HCG PREGNACY TEST KIT 1 PCS) ART. 119903
HCG 114-1 TESTA MED SCHWANGERSCHAFTSTEST 1 ST (HCG PREGNACY TEST KIT 1 PCS) ART. 119914 (IN TRAY)
HCG 114-2 TESTA MED SCHWANGERSCHAFTSTEST 2 ST (HCG PREGNACY TEST KIT PCS) ART. 119910
HCG 114-2 TESTA MED SCHWANGERSCHAFTSTEST 2 ST (HCG PREGNACY TEST KIT PCS) ART. 119915 (IN TRAY)
LH 133-5'S -1 TESTA MED OVULATIONSTEST 5 ST. TESTA MED SCHWANGERSCHAFTSTEST 1 ST. (LH OVULATION TEST KIT 5 PCS + HCG PREGNACY TEST KIT 1PCS) ART. 117808
LH 133-10'S TESTA MED OVULATIONSTEST 10 ST. (LH OVULATION TEST 10 PCS) ART. 117803
HCG 114-LKNG(Green Top) Exeltest Embarazo HCG(HCG Pregnancy test kit 1pcs/12 pcs per outer carton) Art. 1199380
LH133-LKNB(Blue Top) Exeltest Ovulacion LH(5 test kits per pc/6 pcs per outer carton) Art. 1178380
HCG 112 TESTA MED SCHWANGERSCHAFTS FRUHTEST STREIFEN 2 ST. (HCG PREGNACY TEST STRIP 5MM KIT 2 PCS) ART. 441212

Classification: Self-Test IVD

Conformity Assessment

Route: Annex IV

Declaration of conformity:

We herewith declare that the above mentioned product(s) meet the provisions of the Council Directives 98/79/EC for Medical Devices. All supporting documentations is retained under the premises of Atlas Link (Beijing)Technology Co.,Ltd

Standard Applied: EN18113-1,-4 : 2011, EN980:2008, ISO 15223-1:2007+A1, 15223-2:2010
EN13532:2002, EN13612:2002, EN13640:2002, EN ISO14971:2012, EN ISO 13485:2016

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



Atlas Link (Beijing) Technology Co., Ltd

EC Certificate: No.V1 057995 0009 Rev. 02

(Expiry date of the Certificate: 2024-05-26)

Start of CE-Making: Sep. 20th, 2006

Place, Date of Issue: Beijing, May 9, 2021



General Manager:

Chen Jianjian