EC Declaration of Conformity

No. DOC-HCG-1602

Manufacturer:

AccuBioTech Co., Ltd.
Building 10, No.28, Yuhua Road, Beijing, 101300, P.R. China

whose single Authorized Representative:

Medical Device Safety Service GmbH
Schiffgraben 41, 30175 Hannover, Germany
DIMDI No.: DE/0000003258

We, the manufacturer, herewith declare that the products

Accu-Tell® One Step HCG Pregnancy Test for self-testing

EDMA Product Group: HCG - RT & POC

EDMS Code: 12.70.05.02

Model:

Strip: Catalog No.: ABT-FT-A1**,** Product trade/commercial Name: Accu-Tell® One Step HCG Pregnancy Test Strip for self-testing;

Cassette: Catalog No.: ABT-FT-B1, Product trade/commercial Name: Accu-Tell® One Step HCG Pregnancy Test Cassette for self-testing;

Midstream: Catalog No: ABT-FT-C1), Product trade/commercial Name: Accu-Tell® One Step HCG Pregnancy Test Midstream for self-testing.

meet the provisions of Directive 98/79/EC which apply to them.

The medical device has been assigned to devices for self-testing according to the Directive 98/79/EC. It bears the mark

CE 0197

The product concerned has been designed and manufactured under a quality management system according to Annex IV of Directive 98/79/EC.

The above mentioned declaration of conformity is exclusively under the responsibility of

AccuBioTech Co., Ltd.

For and on behalf of ACCUBIOTECH CO., LTD.

Authorized Signature(s)

Beijing, May 1, 2016

Place , date

Andy Wang, Managing Director

Legally binding signature, Function