EC Declaration of Conformity

No. DOC-MLCU-22/01

Manufacturer:

AccuBioTech Co., Ltd.

Building 4, Maohua Industry Park, No. 1, CAIDA Third Street, Nancai Town, Shunyi District, 101399, Beijing, 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

Product Name：Accu-Tell® Multi-Line 6 Drug Cassette (Urine)

Model: Cassette

Catalog Number：ABT-DOA-B116

*(*including system components and accessories*)*

EDMA Product Group: ***Multiple Drugs of Abuse/Toxicology RT & POC***

EDMS Code: 12 70 09 70

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

The medical device has been assigned to devices for other IVD products – Professional Testing Device according to the Directive 98/79/EC. It bears the mark

CE

The product concerned has been designed and manufactured under a quality management system according to Annex III 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, Mar.09, 2022

Place , date

Andy Wang, Managing Director

Legally binding signature, Function

Digitally signed by Moraru Grigore
Date: 2024.04.22 09:35:01 EEST
Reason: MoldSign Signature
Location: Moldova