

Declaration of Conformity

Manufacturer: RUNBIO BIOTECH CO., LTD.
Rongsheng Technological Zone, Univ. Rd., SHANTOU, 515063,
P. R. CHINA

Authorized Representative: YAOTONG S.L
Ausias Marc, 92-98, esc,Center,3a Barcelona 08013, Spain.

PRODUCT: Onestep Pregnancy Urine Tests

CLASSIFICATION: for self-testing according to IVDD

CONFORMITY ASSESSMENT ROUTE: 98/79/EC Annex IV

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



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

STANDARDS APPLIED:

EN ISO 18113-1:2011	EN ISO 18113-4:2011
EN 12286:1998/A1:2000	EN 13532:2002
EN 13640: 2002	EN 13975: 2003
EN 62366:2008	EN 12287:1999
EN13612:2002/AC:2002	EN 13641:2002
EN ISO 14971: 2009	BS EN 980:2008

Compliance of the designated product with the Directive 98/79/EC has been assessed and certified by the Notified Body

NOTIFIED BODY: TUV Rheinland. Product. Safety. GmbH

Address: Rm1600, Beijing Sunflower Tower, NO 37 Maizidian Street, Chaoyang
District, Beijing, P. R. China 100026

Tel: 8610-65666660-125

Fax: 8610-65666667

Contract person: Chen Yuhong

(EC)CERTIFICATE(S): HL 60033621 0001

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