



CE-DOC-H012  
Version 2.0

# EC Declaration of Conformity

In accordance with Directive 98/79/EC

**Legal Manufacturer:** *Healgen Scientific Limited Liability Company*

**Legal Manufacturer Address:** *3818 Fuqua Street, Houston, TX 77047, USA*

Declares, that the products  
Product Name and Model(s)

***see attachment***

Classification: *Other*

Conformity assessment route: *Annex III (EC DECLARATION OF CONFORMITY)*

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint

**EC Representative's Name:** CMC Medical Devices & Drugs S.L

**EC Representative's Address:** C/Horacio Lengo N° 18, CP 29006, Málaga, Spain

to act as our European Authorized Representative as defined in the aforementioned Directive.

I, the undersigned, hereby declare that the medical devices specified above conform with the directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements.

Date Signed: March 31, 2022

Name of authorized signatory: Joyce Pang  
Position held in the company: Vice-President



Attachment to CE-DOC-H012 Version 2.0

One Step Pregnancy Test Strip (Urine)	GAHCG-101a
One Step Pregnancy Test Strip (Urine)	GAHCG-101d
One Step Pregnancy Test Strip (Urine)	GAHCG-101b
One Step Pregnancy Test Cassette (Urine)	GAHCG-102a
One Step Pregnancy Test Cassette (Urine)	GAHCG-102d
One Step Pregnancy Test Cassette (Urine)	GAHCG-102b