



CE-DOC-H176  
Version 1.0

# 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)

Oral Fluid Drug Test	GBDSA-XXXXESI
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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: April 20, 2022

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