

EC Declaration of Conformity

For the following device :

EASYMAX Tag SMBG System

(Product Name)

Is herewith confirmed to comply with the requirements set out in the Council Directive on the harmonization of the laws of Member States concerning In Vitro Diagnostics Directive (98/79/EC).

For the evaluation regarding the product safety aspects, the following standards were applied :
EN ISO 13485 : 2012, EN ISO 14971 : 2012 , EN ISO 15197 : 2015, EN ISO 15223-1 : 2016, EN 61010-1 : 2010, EN 61010-2-101 : 2017, EN 61326-1 : 2013, EN 61326-2-6 : 2013, BS EN 62304 : 2006+AC : 2015, EN62366-1 : 2015, RE Directive 2014/53/EU, EN ISO 18113-1 : 2011, EN ISO 18113-4 : 2011, EN ISO 18113-5 : 2011

The following representative / importer in Europe is responsible for this declaration :

Obelis s.a.

(Representative / Importer Name)

Boulevard Général Wahis 53, B-1030 Brussels, Belgium

(Representative / Importer Address)

Person responsible for making this declaration :

EPS Bio Technology Corp.

(Manufacturer Name)

No.8, R&D Rd. 3, Hsinchu Science Park, 30077, Hsinchu, Taiwan

(Place, Manufacturer Address)

General Manager

(Position/Title)


(Legal Signature)

2020.01.20
(Date)