CE CE

Declaration of Conformity

according to the Directive 98/79/EC
(applicable to IVD Devices of NOT Annex II and NOT self-test)

Manufacturer: Biocomma Limited

Manufacture address: B1605-B1606, Life Science Park, Shenchengtou Creative Factory, Julongshan A Road, Xiuxin Community, Kengzi Street, Pingshan District, Shenzhen City, 518118 Guangdong, P.R. China

Customer service address: 101~106, Block 12, Zhonghaixin Innovation Industrial Zone, No. 12 of Ganli Six Road, Ganli Industrial Zone, Jihua Street, Longgang District, Shenzhen City, 518114 Guangdong, P.R. China

EC Representative: CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo, 18. 29006. Málaga. Spain

We, the manufacturer, declare under our sole responsibility that

The medical device(s)	Product Name	Saliva Collectors
	Type/model, identification of product allowing traceability (Where applicable)	Type A, Type B SC01/SC01B/SC02/SC08/SC08B/SC09/SC11/SC11B/ SC11BV/SC12/SC18/SC18BV/SC19/SC21/SC22/SC28/ SC29/SC31/SC32/SC38/SC39/SC41/SC42/SC48/SC49

of Category **Others of ANNEX I and ANNEX III of IVDD**

These products comply with the essential requirements in accordance with Annex I of the In Vitro Diagnostic medical devices 98/79/EC.

Conformity assessment procedure	**EC Declaration of Conformity (ANNEX I, except point 4 and 7; ANNEX III, except point 6)**
Notified Body (name & number)	**NOT applicable**
Certificate & number	

Name of authorized signatory: Gao Ming Chen
Position held in the company: Chief Executive Officer

For and on behalf of
Biocomma Limited

Signature (on behalf of the manufacturer) Gaoming Chen 2021.8.23

Authorized Signature(s)