



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 Rd, Xiuxin Community, Kengzi St, Pingshan Dist, ShenZhen, 518118 P.R.China

Customer service address: Ground FL, Bdg 12, Zhonghaixin Innovative Industrial Park, Ganli Six Rd, Jihua St, Longgang Dist, Shenzhen, 518114, 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/SC02/SC08/SC09/SC11/SC12/SC18/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
深圳逗点生物技术有限公司

Gaoming Chen

Signature (on behalf of the manufacturer)

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Authorized Signature(s)