



# EC 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, Buji 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**

<b>The medical device(s)</b>	Product Name	Transport and Preservation Medium
	Type/model, identification of product allowing traceability (Where applicable)	YVJ-E/YVJ-E1/YVJ-E2/YVJ-TE/YVJ-TE1/ YVJ-TE2/YVJ-TE3/YVJ-TE4/YVJ-TE5/ YVJ-TE6/YVJ-TE7/YVJ-TE8/YVJ-TE9/ YVJ-TE10/YVJ-TE11/YVJ-TE12/ YMJ-E/YMJ-E1/YMJ-E2/YMJ-TE/YMJ-TE1/ /YMJ-TE2/YMJ-TE3/YMJ-TE4/YMJ-TE5/ YMJ-TE6/YMJ-TE7/YMJ-TE8/YMJ-TE9/ YMJ-TE10/YMJ-TE11/YMJ-TE12

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

**is/are in conformity with the relevant provisions and requirements of Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.**

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) \_\_\_\_\_  
*Authorized Signature(s)*