Declaration of Conformity

According to annex III of the Council Directive 98/79/EC on in vitro diagnostic medical device
We,

Manufacturer's Name: **TCM Biosciences Inc.**
Address: **3F, 3-dong, 15, Pangyo-ro 228beon-gil, Bundang-gu, Seongnam-si, Gyeonggi-do, Republic of Korea, 13487**

Declare under our sole responsibility that the following in vitro diagnostic medical devices other than those covered by annex II and devices for performance evaluation

Product:TCM-Q Corona III

Meet the provisions of the Council Directive 98/79/EC concerning medical devices which apply to them. Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:

- availability of the technical documentation set in Annex III (section 3), allowing the assessment of conformity of the product with the requirements of the Directive.
- the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
- the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

Conformity assessment was performed according to Article 9 (7) and Annex III, section 3.

Our current Quality System is formatted to international standards:

- ISO 13485:2016

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Date of Issue: 06/04/20

Signature:

Dong Jin Shin
CEO, TCM Biosciences, Inc.