

August 21, 2024

Statement

To Whom It May Concern:

This statement has been issued for the following product and should be used to confirm the origin as indicated below.

Product: StemFit™ For Differentiation

Origin: Japan

Quality Information:

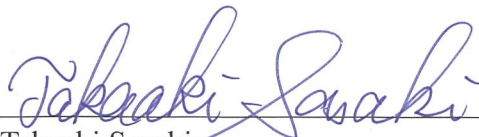
The manufacturing and product release testing of our product are managed in accordance with the GMP standard Ajinomoto formulated for culture media for regenerative medicine. The GMP standard are prepared with reference to ICH Q7 and “PMDA Guidance for Aseptic Manufacturing Processes of Regenerative Medicine Products” .

At this time, Ajinomoto engages a subsidiary, Ajinomoto Kohjin Bio, to manufacture our product in compliance with the above stated GMP standard. Additionally, Ajinomoto has established ISO 9001 certified quality management systems (QMS) and applies its own quality assurance system, the Ajinomoto System of Quality Assurance (ASQUA), to all products and services, to manage the subsidiary under our existing QMS to ensure product quality for our customers.

We, Ajinomoto certify that the product is not of animal or human origin material, which means that the product is composed of materials with animal and/or human origin free, and we prevent any contamination of animal and human materials in our manufacturing process. Please note that the product is only for research and further manufacturing use and is not intended for diagnostic or therapeutic use.

If any additional information is necessary, please contact us at stemfit@asv.ajinomoto.com

Sincerely yours,



Takaaki Sasaki

General Manager

Quality Assurance & Regulatory Affairs Group

Amino Acids Department