

Certification of Substances Department

Certificate of suitability No. CEP 2026-073 - Rev 00

1 *Name of the product:*

2 **BOVINE SERUM ALBUMIN**

3 *Details of holder:*

4 **BIOS BIOTECHNOLOGY COMPANY LTD.**

5 Unit 1102 11 Floor

6 Pacific Plaza

7 418 Des Voeux Road West

8 Sai Ying Pun

9 Hong Kong- Hong Kong Island, Hong Kong

10 SPOR ORG ID: 100054542

11 SPOR LOC ID: 100096660

12 After examination of the information provided on the origin of raw material(s), and the type of tissue(s)
13 used, and the production method, we certify that the product meets the criteria described in the
14 current version of the European Pharmacopoeia monograph **Products with risk of transmitting**
15 **agents of animal spongiform encephalopathies** No. 1483. The approved site(s) of production are
16 included on the following pages.

17 – Countries of origin of source materials:

18 People's Republic of China, with the exclusion of Hong Kong and Macau

19 – Nature of animal tissues used in manufacture:

20 Bovine blood

21 The holder of the certificate should fulfil the following conditions in order to maintain the validity of
22 this certificate.

23 The dossier submitted must be updated in accordance with EDQM guidance on the requirements
24 for revision of certificates of suitability.

25 Production of the substance shall take place in accordance with a suitable quality assurance
26 system, and in accordance with the dossier submitted.

27 Necessary information from the submitted dossier shall be shared with authorised users in order
28 to enable them to evaluate the suitability of this product for its intended use. This includes
29 informing them of any relevant change in the associated dossier.

30 Failure to comply with any of these provisions will render this certificate void.

- 31 This certificate is valid provided that there has been no deterioration in the TSE status of the
32 country(ies) of origin of the source material.
- 33 This certificate is granted within the framework of Resolution AP-CSP (07) 1 adopted by the Council
34 of Europe Public Health Committee (Partial Agreement) (CD-P-SP) in February 2007. With regard
35 to its use in the member states of the European Union/European Economic Area, it is granted in
36 accordance with the provisions of Directive 2001/83/EC and Regulation (EU) 2019/6 as amended,
37 and the related guidelines.
- 38 This certificate is valid from 12 June 2026.

On behalf of the
Director of EDQM