

Certification of Substances Department

**Certificate of suitability
No. R1-CEP 2016-162-Rev 00**

1 *Name of the substance:*
2 **CALF SERUM**

3 *Name of holder:*
4 **BIO WEST SAS**
5 Rue De La Caille
6 France-49340 Nuaillé

7 *Site(s) of production:*
8 **BIO WEST SAS**
9 Rue De La Caille
10 France-49340 Nuaillé

11 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**
12 **R0-CEP 2016-162-REV 00**

13 After examination of the information provided on the origin of raw material(s) and type of tissue(s)
14 used and on the manufacturing process for this substance on the site(s) of production mentioned
15 above, we certify that the substance **CALF SERUM** meets the criteria described in the current
16 version of the monograph Products with risk of transmitting agents of animal spongiform
17 encephalopathies no. 1483 of the European Pharmacopoeia, current edition including supplements.

18 – Country of origin of source materials:
19 France

20 – Nature of animal tissues used in manufacture:
21 Bovine blood

22 The submitted dossier must be updated after any significant change that may alter the quality,
23 safety or efficacy of the substance, or that may alter the risk of transmitting animal spongiform
24 encephalopathy agents.

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

27 Failure to comply with these provisions will render this certificate void.

28 The certificate is valid provided that there has been no deterioration in the TSE status of the
29 country(ies) of origin of the source material.

30 This certificate is renewed from **8 August 2021** according to the provisions of Resolution AP-CSP
31 (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment,
32 and the related guidelines.

33 This certificate has:
34 lines.



On behalf of the
Director of EDQM



Strasbourg, 15 July 2021

DECLARATION OF ACCESS *(to be filled in by the certificate holder under their own responsibility)*

BIO WEST SAS, as holder of the certificate of suitability

R1-CEP 2016-162-Rev 00 for Calf Serum

hereby authorises

(name of the pharmaceutical company)

to use the above-mentioned certificate of suitability in support of their application(s) for the following
Marketing Authorisation(s): *(name of product(s) and marketing number(s), if known)*

The holder also certifies that no significant changes to the operations as described in the CEP dossier
have been made since the granting of this version of the certificate.

Date and Signature *(of the CEP holder)*:

Address: 7 Allée Kastner, CS 30026
F-67081 Strasbourg (France)

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