

Certification of Substances Department

Certificate of suitability
No. R1-CEP 2007-139 - Rev 01

1 *Name of the substance:*

2 **BEEF HEART INFUSION**

3 Cat: 138

4 *Name of holder:*

5 **BIOTECNICA INTERNACIONAL S.A. DE C.V.**

6 Artículo 123 numero 104, Colonia Granjas y Huertos Brenamiel

7 San Jacinto Amilpas

8 Mexico-68285 Oaxaca

9 *Site(s) of production:*

10 **BIOTECNICA INTERNACIONAL S.A. DE C.V.**

11 Artículo 123 numero 104, Colonia Granjas y Huertos Brenamiel

12 San Jacinto Amilpas

13 Mexico-68285 Oaxaca

14 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**
15 **R1-CEP 2007-139 - REV 00**

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

21 – country(ies) of origin of source materials:

22 New Zealand

23 – nature of animal tissues used in manufacture:

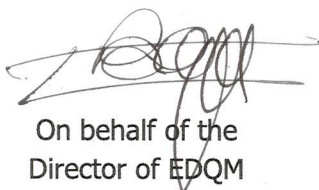
24 Bovine heart

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

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

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

- 31 The 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 renewed from **15 September 2013** according to the provisions of Resolution
34 AP-CSP (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent
35 amendment, and the related guidelines.
- 36 This certificate has:
37 lines.


On behalf of the
Director of EDQM



Strasbourg, 7 April 2022

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

BIOTECNICA INTERNACIONAL S.A. DE C.V., as holder of the certificate of suitability

R1-CEP 2007-139 - Rev 01 for Beef heart infusion

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)*: