

Certification of Substances Department

Certificate of suitability No. CEP 2018-135 - Rev 02

1 *Name of the product:*

2 **BOVINE PERICARDIAL TISSUE**

3 *Details of holder:*

4 **COLLAGEN SOLUTIONS (US) LLC**

5 6455 City West Pkwy

6 United States of America-55344 Eden Prairie, Minnesota

7 SPOR ORG ID: 100049714

8 SPOR LOC ID: 100086563

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

14 – Countries of origin of source materials:
15 New Zealand and United States of America

16 – Nature of animal tissues used in manufacture:
17 Bovine pericardium

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

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

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

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

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

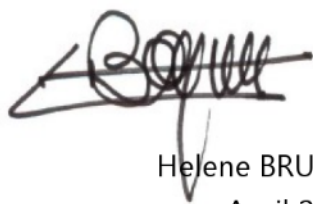
28 This certificate is valid provided that there has been no deterioration in the TSE status of the
29 country(ies) of origin of the source material.

30 This certificate is granted within the framework of Resolution AP-CSP (07) 1 adopted by the Council
31 of Europe Public Health Committee (Partial Agreement) (CD-P-SP) in February 2007. With regard
32 to its use in the member states of the European Union/European Economic Area, it is granted in
33 accordance with the provisions of Directive 2001/83/EC and Regulation (EU) 2019/6 as amended,
34 and the related guidelines.

35 This certificate is valid from 23 April 2024.

On behalf of the
Director of EDQM

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A handwritten signature in dark ink, appearing to read 'H. Bruguera', with a long horizontal stroke extending to the right.

Helene BRUGUERA

April 23, 2024

Site(s) of Production
CEP 2018-135 - Rev 02

SITE(S) OF PRODUCTION:

COLLAGEN SOLUTIONS (US) LLC

6455 City West Pkwy

United States of America-55344 Eden Prairie, Minnesota

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