S. R.

PROCURADORIA-GERAL DA REPÚBLICA

Ref.ª/réf./ref.

APOSTILLE

Convention de La Haye du 5 octobre 1961

1. País/Pays/Country: **Portugal**
   Este documento público/Le présent acte public/This public document
2. Foi assinado por/a été signé par/has been signed by **Maria Fernanda Ralha Henriques Matos**
3. Agindo na qualidade de/agissant dans la qualité de/acting in the capacity of **Directora**
4. E tem o selo de/est revêtu du sceau de/bears the seal of **INFARMED**

Reconhecido/Attesté/Certified

5. Em/à/at **Lisboa**
6. A /le /the **14 de agosto de 2020**
7. Pela Procuradora-Geral da República /par le Procureur général de la République/by the Attorney General
8. Sob o nº /sous le nº /Nº **13571-2020**
9. Selo/sceau/seal
10. Assinatura/signature/signature

Lucília Maria das Neves Franco Morgadinho Gago

A presente Apostila apenas certifica a assinatura, a qualidade em que o signatário do ato atuou e o selo/carimbo que consta do ato. Não certifica o conteúdo do documento para o qual foi emitida.

Cette Apostille ne certifie que la signature, la qualité en laquelle le signataire de l'acte a agi et le sceau/timbre dont cet acte est revêtu. Elle ne certifie pas le contenu du document pour lequel elle a été émise.

This Apostille only certifies the signature, the capacity of the signer and the seal/stamp it bears. It does not certify the content of the document for which it was issued.

La presente Apostilla sólo certifica la firma, la capacidad del signatario y el sello/timbre que ostenta. La Apostilla no certifica el contenido del documento para el cual se expidió.

Rua da Escola Politécnica, n.º 140 1269-269 LISBOA PORTUGAL * Telf.: 21 392 19 00 * 21 394 98 00 * Fax: 21 397 52 55
E-mail: correiopgr@pgr.pt

REPÚBLICA PORTUGUESA
SAÚDE

SNS SERVIÇO NACIONAL DE SAÚDE

Infarmed
Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.

National Authority of Medicines and Health Products, I.P.

CERTIFICATE NUMBER: ***FT059/MH/001/2020***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Portugal confirms the following:
The manufacturer: ***CJSC Sotex PharmFirm***
Site address: ***Bld. 10, bld. 11, bld. 12 Belikovo village,, Bereznyakovskoe rural settlement,Sergiev-Posad municipal district,, Moscow region, 141345, Russian Federation***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC transposed in the following national legislation:
Art.176.º n.º 4 of Decree-Law n.º 176/2006, 30 of August

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2019-09-20*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

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1749-004 Lisboa
Tel.: +351 217 987 100 **Fax**: +351 217 987 316 **Website:** www.infarmed.pt **E-mail**: infarmed@infarmed.pt

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids
1.5	**Packaging**
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical*

Any restrictions related to the scope of this certificate :

Restricted to manufacturing line B.

Clarifying remarks (for public users)

Restricted to manufacturing line B.

2020-03-09

Name and signature of the authorised person of the Competent Authority of Portugal

Ms. Maria Fernanda Ralha Henriques Matos
National Authority of Medicines and Health Products, I.P.
Tel: ***+351 21 7987278***
Fax: ***+351 21 7987257***