2024 -05- 2 1

CHIEF PHARMACEUTICAL INSPECTOR

ISF.405.56.2024.IP.2
WTC/0059_01_01/95

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Article 63(4) of Regulation (EU) No 536/2014

Chief Pharmaceutical Inspector
/the Competent Authority of Poland/

confirms the following:

the manufacturer and importer

BIO-CHIC Spółka z o.o.

ul. Chłodna 56/60, 00-872 Warszawa, POLAND

site address

BIO-CHIC Spółka z o.o.

ul. Chłodna 56/60, 00-872 Warszawa, POLAND

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **116/0059/15** in accordance with Art. 61(1) of Regulation (EU) No 536/2014 Art. 38 and Art. 51a point 5 Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2024, item 686).

From the knowledge gained during inspection of this manufacturer and importer the latest of which was conducted on **21/02/2024**, it is considered that it complies with the Good Manufacturing Practice requirements laid down in Commission Delegated Regulation (EU) 2017/1569.

This certificate reflects the status of the manufacturing and importation 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.

Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/).

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.

acting Chief Pharmaceutical Inspector

Marcin Wójtowicz

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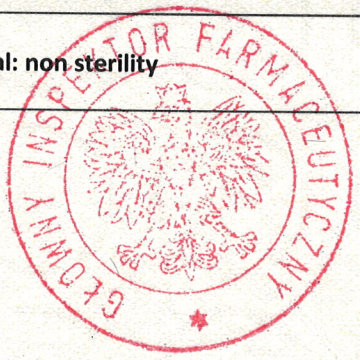
Part 2

Human Medicinal Products

1 OPERACJE WYTWÓRCZE DOTYCZĄCE BADANYCH PRODUKTÓW LECZNICZYCH	
1.6	**Quality control testing**
	1.6.2 Microbiological: non sterility

2 IMPORT BADANEGO PRODUKTU LECZNICZEGO	
2.1	**Quality control testing of imported medicinal products**
	2.1.2 Microbiological: non sterility



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