Chief Pharmaceutical Inspector

IWPS.405.25.2019.KKW.2
WTC/0415_01_02/45

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 15 of Directive 2001/20/EC as amended

Chief Pharmaceutical Inspector
/the Competent Authority of Poland/

confirms the following:

the manufacturer and importer

Health-Med spółka z ograniczoną odpowiedzialnością spółka komandytowa

ul. Walewska 8 lok.5, 04-022 Warszawa, POLAND

site address

Health-Med spółka z ograniczoną odpowiedzialnością spółka komandytowa

ul. Chełmska 30/34, 00-725 Warszawa, POLAND

has been inspected under the national inspection programme in connection with importation authorisation No. **016/0415/15** in accordance with Art. 13 of Directive 2001/20/EC transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2017, item 2211).

From the knowledge gained during inspection of this manufacturer and importer, the latest of which was conducted on **04-05/12/2018**, it is considered that it complies with the Good Manufacturing Practice requirements laid down in Directive 2003/94/EC.

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.

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 EudraGMP. If it does not appear, please contact the issuing authority.

date: 2019 -09- 05

Chief Pharmaceutical Inspector

Paweł Piotrowski

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Chief Pharmaceutical Inspector

Chief Pharmaceutical Inspectorate
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Part 2

Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS	
1.1	**Sterile products**
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.3	**Biological medicinal products**
	1.3.2 Batch certification 1.3.2.6 Human or animal extracted products
1.4	**Other products or processing activity**
	1.4.3 Others: distribution

2 IMPORTATION OF HUMAN INVESTIGATIONAL MEDICINAL PRODUCTS	
2.2	**Batch certification of imported investigational medicinal products**
	2.2.1 Sterile Products 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised **2.2.2 Non-sterile products** **2.2.3 Biological medicinal products** 2.2.3.6 Human or animal extracted products
2.3	**Other importation activities**
	2.3.4 Other: distribution

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

Chief Pharmaceutical Inspector

date: 2019 -03- 05

Paweł Piotrowski

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