



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.

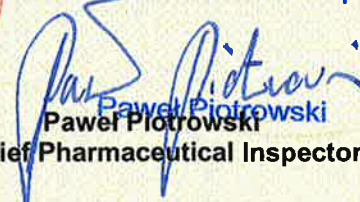
The authenticity of this certificate may be verified in EudraGMP. If it does not appear, please contact the issuing authority.

date: 2019-03-05

Chief Pharmaceutical Inspectorate
ul. Senatorska 12, 00-082 Warszawa, Poland
Tel. +48 22 635 99 51, fax. +48 22 635 99 57



Chief Pharmaceutical Inspector


Paweł Piotrowski
Chief Pharmaceutical Inspector

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



date: 2019 -03- 05

Chief Pharmaceutical Inspectorate
 ul. Senatorska 12 , 00-082 Warszawa, Poland
 Tel. +48 22 635 99 51, fax. +48 22 635 99 57

Chief Pharmaceutical Inspector

Paweł Piotrowski
 Chief Pharmaceutical Inspector