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National Institute of Pharmacy and Nutrition

CERTIFICATE NUMBER: *OGYÉI/17002-4/2016*

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
Art. 15 of Directive 2001/20/EC

The competent authority of Hungary confirms the following:
The manufacturer: ***Medi-Radiopharma Egészségügyi Szervező, Tanácsadó, Szolgáltató és Kereskedelmi Kft. (Medi-Radiopharma Kft.)/ Medi-Radiopharma Ltd.***
Site address: ***Site 2., Gyár utca 2., Budaörs, 2040, Hungary***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***OGYÉI/17002-2/2016*** in accordance with Art. 40 of Directive 2001/83/EC and Art. 13 of Directive 2001/20/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2015-06-03*** , 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 EudraGMP. If it does not appear, please contact the issuing authority.

[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.*

Part 2

Human Medicinal Products Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS	
1.6	**Quality control testing**
	1.6.3 Chemical/Physical
	1.6.4 Biological

Any restrictions related to the scope of this certificate :

Quality control testing activities include radio-chemical testing. Certificate applies to Human Medicinal Products and Investigational Medicinal Products.

Clarifying remarks (for public users)

Quality control testing activities include radio-chemical testing. Certificate applies to Human Medicinal Products and Investigational Medicinal Products.

2016-04-08

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

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