Medicines and Healthcare Products Regulatory Agency

CERTIFICATE NUMBER: ***UK ManA 6180 Insp GMP 6180/88968-0009***

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

Part 1

Issued following an inspection in accordance with :
Art. 80(5) of Directive 2001/82/EC as amended

The competent authority of United Kingdom confirms the following:
The manufacturer: ***SYNERGY HEALTH STERILISATION UK LIMITED***
Site address: ***ROYDSDALE WAY, EUROWAY TRADING ESTATE, BRADFORD, BD4 6SE, United Kingdom***

Has been inspected under the national inspection programme in accordance with Art. 44 of Directive 2001/82/EC transposed in the following national legislation:
The Current Veterinary Medicines Regulations

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2015-03-18*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/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.

---

[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

Veterinary Medicinal Products

1 MANUFACTURING OPERATIONS	
1.4	**Other products or manufacturing activity**
	1.4.2 Sterilisation of active substance/ excipients/ finished product 1.4.2.5 Gamma irradiation

Clarifying remarks (for public users)

Following a risk-based review of GMP compliance information conducted on 12th September 2018, the validity period of this certificate is extended to 12th September 2019. This certificate should be used in combination with the relevant Manufacturer's Authorisation/Registration.

2018-09-12

Name and signature of the authorised person of the Competent Authority of United Kingdom

---

Confidential
Medicines and Healthcare Products Regulatory Agency
Tel: ***Confidential***
Fax: ***Confidential***