



MHRA
Regulating Medicines and Medical Devices

MHRA

151 Buckingham Palace Road
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United Kingdom

mhra.gov.uk

RESTRICTED – COMMERCIAL
Miss Kristen Middleton
SYNERGY HEALTH STERILISATION UK LIMITED
BRUNEL CLOSE
DRAYTON FIELDS INDUSTRIAL ESTATE
DAVENTRY
NORTHAMPTONSHIRE
NN11 8RB
UNITED KINGDOM



Medicines and Healthcare products Regulatory Agency

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC.

The competent authority of the United Kingdom confirms the following:

The manufacturer	SYNERGY HEALTH STERILISATION UK LIMITED
Site address	BRUNEL CLOSE DRAYTON FIELDS INDUSTRIAL ESTATE DAVENTRY NORTHAMPTONSHIRE NN11 8RB UNITED KINGDOM

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. MIA 6180 in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation: The Human Medicines Regulations 2012 (SI 2012/1916).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 17/12/2014, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC.

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 only valid 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.



Part 2

Human Medicinal Products

1. MANUFACTURING OPERATIONS

1.1 Sterile products

Not Authorised

1.2 Non-sterile products

Not Authorised

1.3 Biological medicinal products

Not Authorised

1.4 Other products or manufacturing activity

1.4.2 Sterilisation of active substances/excipients/finished product

1.4.2.5 Gamma irradiation

1.4.2.6 Electron Beam

1.5 Packaging

Not Authorised

1.6 Quality control testing

Not Authorised

2. IMPORTATION OF MEDICINAL PRODUCTS

2.1 Quality control testing of imported medicinal products

Not Authorised

2.2 Batch certification of imported medicinal products

Not Authorised

2.3 Other importation activities

Not Authorised



3. MANUFACTURING OPERATIONS

3.1 Manufacture of Active Substance by Chemical Synthesis

Not Authorised

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

Not Authorised

3.6 Quality Control Testing

Not Authorised

4 Other Activities

Not Authorised



Any restrictions or clarifying remarks related to the scope of this certificate:

N/A

1. Building(s)/Area(s)

N/A

2. Room(s)

N/A

3. Line(s) Equipment(s)

N/A

4. QC testing

N/A

5. Medicinal Product(s)/IMP(s)

N/A

**Name of the authorised person of the
Competent Authority of the United Kingdom**

Kevin Page
GMP Inspector
kevin.page@mhra.gsi.gov.uk

Date: 06/03/2015

