



Medicines & Healthcare products  
Regulatory Agency



**MHRA**

10 South Colonnade  
Canary Wharf  
London  
E14 4PU  
United Kingdom

[gov.uk/mhra](https://www.gov.uk/mhra)

RESTRICTED – COMMERCIAL  
Ms Joanna Bula  
SYNERGY HEALTH STERILISATION UK LIMITED  
ROYDSDALE WAY  
EUROWAY TRADING ESTATE  
BRADFORD  
BD4 6SE  
UNITED KINGDOM



Certificate No: UK MIA 6180 Insp GMP 6180/88968-0014

## Medicines and Healthcare products Regulatory Agency

### CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

#### Part 1

**Issued following an inspection in accordance with Regulation 331A of The Human Medicines Regulation 2012 (SI 2012/1916)**

The competent authority of the 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 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 06/09/2022, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Regulation B17 of the Human Medicines Regulations 2012 (as amended).

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 MHRA-GMDP database. If it does not appear please contact the issuing authority.



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## 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

#### 1.5 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



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### **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



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

The scope of this certificate includes both the Bradford Pallet Plant process and the separate Radiation Technology Centre (RTC) process that are performed at this site.

1. Building(s)/Area(s)

N/A

2. Room(s)

N/A

3. Line(s) Equipment(s)

Includes both Radiation Technology Centre (RTC) process and Bradford Pallet Plant process that are performed at the site.

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**

**Dr A J Gray**  
**Head of Inspectorate**  
**inspectionplanning@mhra.gov.uk**

**Date: 03/11/2022**