Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 1811

2: Name of authorisation holder BARD PHARMACEUTICALS LIMITED

BARD PHARMACEUTICALS LIMITED, UNIT 191, CAMBRIDGE

3: Address(es) of manufacturing site(s) SCIENCE PARK, MILTON ROAD, CAMBRIDGE, CB4 0GW, UNITED

KINGDOM

BARD PHARMACEUTICALS LIMITED, UNIT 198, CAMBRIDGE

4: Legally registered address of authorisation holder SCIENCE PARK, MILTON ROAD, CAMBRIDGE, CB4 0AB, UNITED

KINGDOM

5: Scope of authorisation and dosage forms

ANNEX 1 and/ or ANNEX 2

6: Legal Basis of authorisation

Part 6 of The Medicines for Human Use (Clinical Trials) Regulations

2004 [SI 2004/1031]

7: Name of responsible officer of the competent authority

of the member state granting the manufacturing

authorisation

Confidential

8: Authorisation Date 21/04/2023

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

BARD PHARMACEUTICALS LIMITED, UNIT 191, CAMBRIDGE SCIENCE PARK, MILTON ROAD, CAMBRIDGE, CB4 0GW, UNITED KINGDOM

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.2] Non-sterile investigational medicinal products

[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)

[1.2.1.1] Capsules, hard shell

[1.2.1.13] Tablets

[1.6] Quality control testing

[1.6.3] Chemical/Physical

Issue Date: 21 Apr 2023