Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number

2: Name of authorisation holder

3: Address(es) of manufacturing site(s)

4: Legally registered address of authorisation holder

5: Scope of authorisation and dosage forms

6: Legal Basis of authorisation

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation

8: Authorisation Date

9: Annexes attached

UK MIA 5920

BECTON DICKINSON UK LIMITED

BECTON DICKINSON UK LIMITED, 1030 ESKDALE ROAD, WINNERSH, WOKINGHAM, RG41 5TS, UNITED KINGDOM

BECTON DICKINSON UK LIMITED, 1030 ESKDALE ROAD, WINNERSH, WOKINGHAM, RG41 5TS, UNITED KINGDOM

ANNEX 1 and/ or ANNEX 2

Regulation 17 of The Human Medicines Regulations 2012 (SI

2012/1916)

Confidential

13/07/2021

Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

BECTON DICKINSON UK LIMITED, 1030 ESKDALE ROAD, WINNERSH, WOKINGHAM, RG41 5TS, UNITED KINGDOM

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Products

[1.1.1] Aseptically prepared (processing operations for the following dosage forms)

[1.1.1.6] Other aseptically prepared products

Site of Fiscal Importation from parent company based in Swetzerland who hold title to the stock in t

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.2] Batch certification of imported medicinal products

[2.2.1] Sterile Products

[2.2.1.2] Terminally sterilised

Issue Date: 13 Jul 2021