

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 21538

2: Name of authorisation holder TERUMO BCT LTD.

3: Address(es) of manufacturing site(s) TERUMO BCT LIMITED, OLD BELFAST ROAD,
MILLBROOK, LARNE, BT40 2SH, UNITED KINGDOM

4: Legally registered address of authorisation holder TERUMO BCT LTD., OLD BELFAST ROAD,
MILLBROOK, LARNE, BT40 2SH, UNITED KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

6: Legal Basis of authorisation Regulation 17 of The Human Medicines Regulations 2012
(SI 2012/1916)

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

8: Authorisation Date 18/12/2023

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

TERUMO BCT LIMITED, OLD BELFAST ROAD, MILLBROOK, LARNE, BT40 2SH, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Products [1.1.2] Terminally Sterilised (processing operations for the following dosage forms) [1.1.2.1] Large volume liquids [1.1.2.3] Small volume liquids [1.2] Non-sterile products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.5] Liquids for external use [1.4] Other products or manufacturing activity [1.4.2] Sterilisation of active substances/excipients/finished products:

[1.4.2.3] Moist heat

[1.5] Packaging

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.1] Microbiological: sterility

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical