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	17/11/2025
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:

MHRA-GMDP MHRA

[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

MHRA-GMDP