

# 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

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| Human Medicinal Products   |
| Authorised Operations  |
| MANUFACTURING OPERATIONS (according to part 1)   |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.1 ] Sterile Products</b><br>[ 1.1.2 ] Terminally Sterilised (processing operations for the following dosage forms)<br>[ 1.1.2.1 ] Large volume liquids<br>[ 1.1.2.3 ] Small volume liquids<br><b>[ 1.2 ] Non-sterile products</b><br>[ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms)<br>[ 1.2.1.5 ] Liquids for external use<br><b>[ 1.4 ] Other products or manufacturing activity</b><br>[ 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