

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA 21538
<b>2: Name of authorisation holder</b>	TERUMO BCT LTD.
<b>3: Address(es) of manufacturing site(s)</b>	TERUMO BCT LIMITED, OLD BELFAST ROAD, MILLBROOK, LARNE, BT40 2SH, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	TERUMO BCT LTD., OLD BELFAST ROAD, MILLBROOK, LARNE, BT40 2SH, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	18/12/2023
<b>9: Annexes attached</b>	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)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Products</b> [ 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 <b>[ 1.2 ] Non-sterile products</b> [ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms) [ 1.2.1.5 ] Liquids for external use <b>[ 1.4 ] Other products or manufacturing activity</b> [ 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