Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK MIA 21538 Insp GMP 21538/21804-0014[H]

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER*(1),(2)*

Part 1

Issued following an inspection in accordance with :
Regulation 331A of The Human Medicines Regulations 2012 (SI 2012/1916)

The competent authority of United Kingdom confirms the following :

The Manufacturer : TERUMO BCT LIMITED

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

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. UK MIA 21538 in accordance with Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 07/02/2022 , it is considered that it complies with

- The principles and guidelines of Good Manufacturing Practice laid down in Regulation B17 of the Human Medicines Regulations 2012 (as amended)

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in MHRA-GMDP. If it does not appear, please contact the issuing authority.

- *(1) Guidance on the interpretation of this template can be found in the Help menu of MHRA-GMDP database.*
- *(2) These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

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

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[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

12/04/2023 Name and signature of the authorised person of the Competent Authority of United Kingdom

Confidential

Medicines and Healthcare products Regulatory Agency

Tel : Confidential

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