AGENZIA ITALIANA DEL FARMACO

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC

The competent authority of Italy confirms the following:
The manufacturer BIOREP S.R.L.
Site address VIA OLGETTINA, 60 MILANO (MI) 20132 Italia

ORG-100028828 / LOC-100046016

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in the following national legislation: **D.L. n. 219 of 24th April 2006 art. 53**

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 2025/01/23, it is considered that it complies with the Good Manufacturing Practice requirements referred to in the principles of GMP for active substances referred to in Article 47 of Directive 2001/83/EC.

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.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

Agenzia Italiana del Farmaco Via del Tritone, 181 - 00187 Roma (+39) 06.59.78.401 www.aifa.gov.it

Part 2

Name and address of the site:

BIOREP S.R.L.- VIA OLGETTINA, 60 MILANO (MI) 20132 Italia

Name of the active Substances manufactured or imported: ACTIVE SUBSTANCES (STERILE AND/OR BIOLOGICAL AND/OR FROM HUMAN AND ANIMAL TISSUES, ORGANS, FLUIDS)

3. Manufacturing Operations - Active Substances

ACTIVE SUBSTANCES (STERILE AND/OR BIOLOGICAL AND/OR FROM HUMAN AND ANIMAL TISSUES, ORGANS, FLUIDS)

3.3 Manufacture of Active Substance using Biological Processes

3.3.5. Other

storage of MCB and/or WCB

Restrictions or clarifying remarks:

According to Italian legislation, all the biological active substances and/or active substances deriving from human and animal tissues, organs, fluids listed in this document are authorized according to art. 40 of Dir. 2001/83/EC. On a risk-based approach, the validity of the GMP certificate for this manufacturing site is not more than 48 months from the latest general GMP inspection conducted on 2025/01/23, except for AIFA's re-evaluation of the risk profile

Rome, 2025/08/06

Name and signature of the authorised person of the Competent Authority of Republic of Italy

Michele Marangi
AIFA - GMP Inspections and Manufacturing Authorizations of APIs Office

Electronically signed according to the Italian legislation

Stamp duty paid according to the current Italian legislation.

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