



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 MIAT S.P.A.

Site address Via Belinzaghi, 5, MILANO (MI), 20159, Italia

ORG-100007762 / LOC-100054289

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 2025/09/18, 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.

Part 2

Name and address of the site:

MIAT S.P.A.- Via Belinzaghi, 5, MILANO (MI), 20159, Italia

Name of the active Substances manufactured or imported:

URSODEOXYCHOLIC ACID
SODIUM HYALURONATE
TESTOSTERONE
TIOCONAZOLE

4. Other Activities - Active Substance:

Importation of:

URSODEOXYCHOLIC ACID
SODIUM HYALURONATE
TESTOSTERONE
TIOCONAZOLE

Restrictions or clarifying remarks:

Imported active substances (AS) can be given only to medicinal products/AS manufacturers for human use. According to Italian legislation, all the biological active substances and/or active substances deriving from human and animal tissues, organs, fluids 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 2025/09/18, except for AIFA's re-evaluation of the risk profile.

Rome, 2025/11/17

**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.