

Certificate No: IT/23/H/2024

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 PIAZZA PASOLINI, 2 - 20159 MILANO (MI)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 16/2024 dated 01/24/2024 in accordance with Art. 40 of Directive 2001/83/EC/ transposed in the following national legislation: D. Lvo 219/2006 Art. 50.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 11/28/2023, it is considered that it complies with the Good Manufacturing Practice requirements referred to in The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/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, after which time the issuing authority should be consulted.

The authenticity of this certificate may be verified with the issuing authority.

Part 2

Name and address of the site: MIAT S.P.A. - PIAZZA PASOLINI, 2 , 20159 MILANO(MI)

Human Medicinal Products

Authorised Operations

Importation of medicinal products (Part 2)

PART 2 - IMPORTATION OF MEDICAL PRODUCTS

2.2	Batch certification only (list of product types)
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	2.2.2 <i>Non-sterile products</i>
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Any restrictions or clarifying remarks related to the scope of these Importing operations:

2.2.2 Non-sterile products: transdermal Patches; impregnated matrices;



Rome, 01/24/2024

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

Angela Del Vecchio
GMP Inspections and Manufacturing
Authorizations of Medicinal Products Office

STAMP DUTY PAID ACCORDING TO THE CURRENT ITALIAN LAW

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