LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Swedish Medical Products Agency

CERTIFICATE NUMBER: ***SE-HI-GMP-24-022954***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

Part 1

Issued following an inspection in accordance with
Art. 63 of Regulation (EU) 536/2014

The competent authority of Sweden confirms the following:
The manufacturer: ***Tamro AB***
Site address: ***Importgatan 18-20, Backa, Hisings Backa, 422 46, Sweden***
OMS Organisation Id. / OMS Location Id.: ***ORG-100012530 / LOC-100018510***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***SE-HI-MIA-24-022954*** in accordance with Art. 61 of Regulation (EU) No 536/2014.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2022-03-24***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in Part 2.[3]

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. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). 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 EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph Art. 15 of Directive 2001/20/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

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Part 2

Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS	
1.5	**Packaging**
	1.5.2 Secondary packaging

Clarifying remarks (for public users)

1.5.2 Secondary packaging including labelling, re-labelling and additional labelling for clinical trials.

2024-03-13

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Name and signature of the authorised person of the Competent Authority of Sweden

Bengt Berglund
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