REPUBLIC OF ESTONIA
AGENCY OF MEDICINES

Estonian State Agency of Medicines

Certificate No: JV-17/23/14

CERTIFICATE OF GDP COMPLIANCE OF A WHOLESALE DISTRIBUTOR

Issued following an inspection in accordance with Art. 111 of Directive 2001/83/EC as amended.

The competent authority of Estonia confirms the following:

The wholesale distributor ***AS Oribalt Tallinn***

Site address ***Harju maakond, Rae vald, Lehmja küla, Kõrtsi tee 9, ESTONIA***

Has been inspected under the national inspection programme in connection with authorisation number 464 in accordance with Art. 77 (1) of Directive 2001/83/EC transposed in the following national legislation: Medicinal Products Act (public. ref: Riigi Teataja = State Gazette www.riigiteataja.ee) § 26 subsection 1.

From the knowledge gained during inspection of this wholesale distributor, the latest of which was conducted on ***2023-11-08***, it is considered that it complies with the Good Distribution Practice requirements laid down in Article 84 of Directive 2001/83/EC.

This certificate reflects the status of the premises at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than five years have elapsed since the date of that inspection. However, this period of validity may be reduced 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.

The authenticity of this certificate may be verified in the Union database http://eudragmp.ema.europa.eu
If it does not appear, please contact the issuing authority.

Any restrictions or clarifying remarks related to the scope of this certificate:
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2023-12-07 Name and signature of the authorised person of the competent authority of Estonia

Sirlin Valgi-Tann
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Details of the authorisation can be found in the Union Database http://eudragmp.ema.europa.eu