

Certificate No: MT/009HW/2023

## CERTIFICATE OF GDP COMPLIANCE OF A WHOLESALE DISTRIBUTOR

Issued following an inspection in accordance with Art. 111 of Directive 2001/83/EC The competent authority of Malta confirms the following:

The wholesale distributor: Macure Healthcare Limited

Site address: 62 Archlight Building, Triq L-Gharbiel, Is-Swieqi, SWQ 3251, Malta

Has been inspected under the national inspection programme in connection with authorisation number WL141 in accordance with Art. 77 (1) of Directive 2001/83/EC transposed in the following national legislation: Medicines Act 2003 Part III Title III Art 54

From the knowledge gained during inspection of this wholesale distributor, the latest of which was conducted on 1<sup>st</sup> February 2023, 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. If it does not appear please contact the issuing authority.

Any restrictions or clarifying remarks related to the scope of this certificate: This site is not certified for holding of human medicinal products.

28th March 2023

Dr. Mark Cilia

Director Inspectorate & Enforcement Directorate

Medicines Authority Tel: 00356 234 39 119 Fax: 00356 234 39 161

Details of the authorisation can be found in the Union Database.

Sir Temi Żammit Buildings, Life Sciences Park, SGN 3000, San Gv info.medicinesauthority@gov.mt | (+356) 23 439 000 www.medicinesauthority.gov.mt







