National Authority Of Medicines And Health Products

Certificate No: A016/23/H/004/2025/I02/S1

CERTIFICATE OF GDP COMPLIANCE OF A WHOLESALE DISTRIBUTOR

Issued following an inspection in accordance with Art. 111(1) of Directive 2001/83/EC

The competent authority of Portugal confirms the following:

The wholesale distributor (WDA): Sparmedix Distribuicao Farmaceutica Lda.

Site address: Rua De Delfim Ferreira 323, Porto, 4100-201

OMS Identifiers: (ORG-100037129 / LOC-100058673)

Has been inspected under the national inspection programme in connection with authorisation number A016/23/H/004/2025 in accordance with Art. 77(1) of Directive 2001/83/EC.

Scope of certificate: Human medicinal products

From the knowledge gained during inspection of this wholesale distributor, the latest of which was conducted on 2025-11-06, 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(For All Users):

National legal basis of authorisation: Art. 177.º (10) of Decree-law 176/2006, of 30th August.

Updating of the Certificate, regarding a renewal of the latest Inspection Date of the Certificate of GDP Compliance.

2026-01-26

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

Maria Fernanda Ralha

Assinado de forma digital por Maria Fernanda Ralha
Dados: 2026.01.28 18:54:37 Z

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