

COUNCIL OF EUROPE

European Directorate for the Quality of Medicines & HealthCare

OMCL NETWORK QUALITY MANAGEMENT SYSTEM

ATTESTATION

The EDQM, European Directorate for the Quality of Medicines & HealthCare, hereby declares that

Infarmed I.P. National Authority for Medicines and Health

Parque de Saúde de Lisboa, Av. do Brasil n.º 53, 1749-004 Lisbon, Portugal

Sections audited: Pharmaceutical Chemistry and Technology Laboratory, Biology and Microbiology Laboratory

has been audited in accordance with the EDQM instruction *ISO7/02* on the OMCL Network Mutual Joint Audit Scheme.

The above-mentioned OMCL is entitled to declare that it has satisfactorily implemented a Quality Management System in accordance with *ISO/IEC 17025*, with the relevant texts of the *European Pharmacopoeia*, with the *Quality Management Guidelines* and the *Terms of Reference* of the General European OMCL Network.

Detailed information can be found in the Audit Report, which is consigned in document *PA/PH/OMCL-QA (24) 22 DEF* and the Follow-up Report *PA/PH/OMCL-QA (25) 22 DEF* corresponding to the **MJA 07/24**, as well as in the enclosed Scope of Assessment. The original documents are archived at the Intergovernmental Committees and Networks Department (ICND) of the EDQM.

Attestation number: **EDQM/MJA-214**

Strasbourg, 19 October 2025
Valid until: **25 November 2028**


Laurent Mallet
Head of ICND, EDQM