

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

Agency for Medicinal Products and Medical Devices (HALMED)

Ksaverska cesta 4, 10000 Zagreb, Croatia

Section audited: Physico-Chemical Laboratory Department, Biological Laboratory Department

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 (25) 19 DEF* and the Follow-up Report *PA/PH/OMCL-QA (26) 08 DEF* corresponding to the **MJA 12/25**, 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-221*

Strasbourg, 9 April 2026
Valid until: 24 September 2029


Laurent Mallet
Head of ICND, EDQM