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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

BASG/AGES Austrian Federal Office for Safety in Health Care

OMCL-AT_BASG-B: 1160 Vienna, Possingergasse 38 and OMCL-AT_BASG-C: 1220 Vienna, Spargelfeldstr. 191

Sections audited: Dept. Analytics of Biological Medicinal Products (BAMA, OMCL-AT_BASG-B); Dept. Analytics of Chemical-pharmaceutical Medicinal Products (CPAA, OMCL-AT_BASG-C); Dept. Quality Management (QMGT)

has been audited in accordance with the EDQM instruction IS07/02 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) 24 DEF* and the Follow-up Report *PA/PH/OMCL-QA (25) 09 DEF* corresponding to the **MJA 09/24**, 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-206

Strasbourg, 17 June 2025

Valid until: 15 December 2028

Laurent Mallet

Head of ICND, EDQM