

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

Paul-Ehrlich-Institut - Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Straße 51-59, 63225 Langen, Germany

Sections audited: 1/2; 1/3; 3/1, 312, 4/2, 4/3; 5/1, 7/3

has been audited in accordance with the EDQM instruction 157/02 on the OMCL 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.

Detailed information can be found in the Audit Report, which is consigned in document PA/PH/OMCL-QA (16) 16 DEF and the follow-up report PA/PH/OMCL-QA (17) 05 DEF corresponding to the MJA 07/16, and in the enclosed Scope of Assessment. The original documents are archived at the Department of Biological Standardisation, OMCL Network & HealthCare (DBO) of the EDQM and the Director of the OMCL has received a certified copy.

Attestation number: EDQM/MJA-116

Strasbourg, 8 March 2017

Valid until: September 2020



Dr. Karl-Heinz Buchheit

Head of DBQ EDQM

[Addendum Note on the status of validity of the MJA attestation \(Attestation Number: EDQM/MJA-116\)](#)

The Addendum Note is not part of the MJA attestation.

PEI has been authorised to publish this statement in agreement with EDQM.

Due to the COVID-19 crisis, the Mutual Joint Audit carried out by the EDQM/OMCL Network at the OMCL located at the Paul-Ehrlich-Institute has been postponed to 2021. According to an internal OMCL Guideline document on rules for the use of the MJA logo, the EDQM exceptionally approved the use of the MJA logo until the MJA renewal process is completed.