Declaration on pharmacogenetic Analysis

Scope

PharmGenetix GmbH, Sonystrasse 20, A-5081 Anif/Niederalm hereby declares that the methods used in the pharmacogenetic analysis are in accordance with REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND THE COUNCIL of April 5, 2017 on in vitro diagnostics, Article 5, paragraph 5, as in-vitro diagnostics from in-house production for internal use (LDT - Laboratory Developed Tests).

Regulatory Requirements

The methods for pharmacogenetic analysis meet the safety and performance requirements according to REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND THE COUNCIL of April 5, 2017 on in vitro diagnostics, Annex I, and are applied within the certified quality management system of PharmGenetix GmbH.

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