

Article 5(5) Public Declaration

PGx Interpretation Service

Last updated: 23 September 2026

Health institution

Abomics Oy (Business ID 2544609-2), Yliopistonkatu 31, 20100 Turku, Finland

Device

PGx Interpretation Service: in-house pharmacogenetic interpretation software developed, maintained and operated solely by Abomics Oy. The software is kept under configuration and change control within the Abomics Quality Management System, and the release in use at any given time is recorded there and available to the competent authority on request.

Intended Purpose

The PGx Interpretation Service processes genetic test result data and generates patient-specific pharmacogenetic reports. The service interprets pharmacogenetically relevant genotypes and phenotypes and provides information intended to support healthcare professionals in personalized medication management and clinical decision-making.

Classification

The PGx Interpretation Service is an in-house IVD manufactured and used by Abomics in accordance with Article 5(5) of Regulation (EU) 2017/746. Under Rule 3(i) of Annex VIII to that Regulation, it corresponds to a Class C in vitro diagnostic medical device. It is not CE-marked or placed on the market.

Use Within the Health Institution

The PGx Interpretation Service is operated exclusively by Abomics. All genetic data interpretation, expert review and report generation are performed within Abomics systems and processes.

The device itself is not transferred, licensed, distributed or otherwise made available for independent use by another legal entity. Healthcare providers, laboratories, healthcare professionals and patients may receive or access the reports generated by the service; however, such reports constitute the output of the service and not the device itself.

Accordingly, Abomics remains the sole health institution manufacturing and using the in-house IVD device in accordance with Article 5(5) of Regulation (EU) 2017/746.

Declaration

Abomics Oy declares that the PGx Interpretation Service meets the applicable general safety and performance requirements set out in Annex I to Regulation (EU) 2017/746. No applicable requirements have been identified as not fully met.

Document control: The approved master and supporting evidence are maintained within the Abomics Quality Management System. This declaration is made publicly available in accordance with Article 5(5)(f) of Regulation (EU) 2017/746.