PRECISION for medicine

Public Declaration Regarding the Manufacture and Use of In-House Devices by Health Institutions

Name of Health Institution: Precision for Medicine GmbH

Address: Barbara-McClintock-Str. 6 · 12489 Berlin Germany

Precision for Medicine GmbH declares that the devices described in the accompanying table are only manufactured and used in **Precision for Medicine GmbH** and do meet the applicable general safety and performance requirements (GSPR) of the in vitro diagnostic medical devices Regulation (EU 2017/746). A reasoned justification is provided in case applicable general safety and performance requirements are not fully met.

Date and location:
19.08.2024 Berlin
Name: Sven Olek

Function: Managing Director Lab Management & Operations

Signature of responsible person(s):

DocuSigned by:
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Device identification (e.g., name, description, reference number)	**Device type**	**Risk class of the device**	**Intended purpose**	**Applicable GSPR fully met? (Y/N)**	**Information on and justification for applicable GSPR that are not fully met (using the numbering as in Annex I of the IVDR**
PDAC KRAS Assay	IVD	C	The PDAC KRAS Assay is a qualitative nucleic acid test intended for use as an aid in the identification of patients with resected and advanced (metastatic and locally advanced) KRAS G12D and G12V mutated pancreatic ductal adenocarcinoma (PDAC). The PDAC KRAS Assay is used with the therascreen® KRAS RGQ PCR Kit and the QIAamp® DSP DNA FFPE Tissue Kit to test DNA extracted from formalin-fixed and paraffin-embedded (FFPE) tumor tissue on the Rotor-Gene® Q MDx 5plex HRM Instrument. The assay will be performed as a single laboratory testing service at Precision for Medicine GmbH located in Berlin, Germany.	Y	Not Applicable

Revision History		
Version	***Date***	***Changes***
Version 1	August 15, 2024	Initial release