

PUBLIC DECLARATION

According to Article 5(5)(f) of Regulation (EU) 2017/746 (IVDR)

Health Institution:

Transhelix Clinical and Molecular Pathology Laboratory
zh.k. Studentski grad, Prof. Petar Dzhidrov Street 2, 1700 Sofia, Bulgaria

Device:

AmoyDx KRAS Mutation Detection Kit (originally intended for KRAS mutation testing in colorectal cancer).

Actual Intended Use:

KRAS genotyping in non-small cell lung cancer (NSCLC) tumour samples for diagnostic purposes within Transhelix.

Compliance:

Transhelix Laboratory declares that the device meets the applicable General Safety and Performance Requirements (Annex I, IVDR). Deviations related to its use in NSCLC are justified through internal analytical verification and scientific evidence supporting the clinical relevance of KRAS mutations in NSCLC.

Justification under Article 5(5)(d):

The test provides rapid turnaround time and high analytical specificity exclusively for KRAS mutations. Available CE-marked alternatives can be slower and financially less favourable for the patient population.

Publication:

This declaration is made publicly available in accordance with Article 5(5)(f) of the IVDR.

Date: January 2026

Responsible Person: Laboratory Director, Transhelix