Device Schedule:

Intended Purpose as per the Instructions for Use:

The **cobas® liat** SARS-CoV-2 & Influenza A/B v2 nucleic acid test is an automated rapid multiplex real-time reverse transcription polymerase chain reaction (RT-PCR) test intended for the simultaneous qualitative detection and differentiation of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), influenza A virus and influenza B virus nucleic acids in self-collected anterior nasal (nasal) swab specimens (directly observed by a healthcare-provider) and healthcare provider-collected nasal swab and nasopharyngeal swab specimens from individuals with signs or symptoms of respiratory tract infection. Clinical signs and symptoms of respiratory tract infection due to SARS-CoV-2 and influenza can be similar.

The test is meant to be used in conjunction with other clinical and epidemiological information and laboratory findings. SARS-CoV-2, influenza A and influenza B nucleic acids are generally detectable in nasal swab and nasopharyngeal swab specimens during the acute phase of infection. Negative results do not preclude SARS-CoV-2 and/or influenza infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions. Conversely, positive results do not rule out co-infection with other organisms. The agent(s) detected may not be the definite cause of disease.

The cobas® liat SARS-CoV-2 & Influenza A/B v2 nucleic acid test is intended for professional use in a point of care location, near-patient setting or clinical laboratory.

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**	**Basic UDI-DI**
cobas® liat SARS-CoV-2 & Influenza A/B v2 nucleic acid test	09048634190	IVR 0503	Class B near-patient test	761333603136AL