Device Schedule:

Intended Purpose as per the Instructions for Use
The cobas® SARS-CoV-2 Nucleic acid test for use on the cobas® Liat® System (cobas® SARS-CoV-2) is an automated real-time RT-PCR assay intended for the rapid in vitro qualitative detection of SARS-CoV-2 in self-collected nasal swabs (collected in a healthcare setting with instruction by a healthcare provider) and healthcare provider-collected nasopharyngeal and nasal swabs from either individuals suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider or from individuals without symptoms or other reasons to suspect COVID-19.

cobas® SARS-CoV-2 is intended for use in the detection of SARS-CoV-2 in clinical specimens. SARS-CoV-2 viral RNA is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results are indicative of active infection but do not rule out co-infection with other pathogens not detected by the test. Clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. The agent detected may not be the definite cause of disease.

Negative results do not preclude infection from SARS-CoV-2 and should not be used as the sole basis for diagnosis, treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and/or epidemiological information.

cobas® SARS-CoV-2 is intended for use by health professionals or trained operators who are proficient in using the cobas® Liat® System in Near Patient Testing, Point of Care (POC) or in a clinical laboratory setting.

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**	**Basic UDI-DI**
cobas® SARS-CoV-2 Nucleic acid test for use on the cobas® Liat® System	09408592190	IVR 0503	Class D near-patient test	761333602427AT
cobas® SARS-CoV-2 Quality Control Kit for use on the cobas® Liat® System	09408835190	IVR 0503	Class D near-patient test	761333602427AT