Device Schedule:

Intended Purpose as per the Instructions for Use:

cobas® SARS-CoV-2 Duo for use on the **cobas®** 5800/6800/8800 Systems (**cobas®** SARS-CoV-2 Duo) is an automated real-time RT-PCR assay for the in vitro qualitative and quantitative detection of SARS-CoV-2 RNA in healthcare provider-instructed self-collected nasal (anterior nares and mid-turbinate) swab specimens (collected on site), and healthcare provider-collected nasal and nasopharyngeal swab specimens collected from individuals suspected of COVID-19 by their healthcare provider. **cobas®** SARS-CoV-2 Duo is intended for use as an aid in the diagnosis of patients suspected of COVID-19 by their healthcare provider.

The SARS-CoV-2 RNA is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, recent exposures, and epidemiological information.

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**	**Basic UDI-DI**
cobas® SARS-CoV-2 Duo	09500111190	IVR 0503	Class D	761333602769BS
cobas® SARS-CoV-2 Duo Control Kit	09500120190	IVR 0503	Class D	761333602769BS