Device Schedule:

cobas® Respiratory flex for use on the **cobas**® 5800/6800/8800 Systems (**cobas**® Respiratory flex) is an automated, multiplex, nucleic acid test that utilizes real-time polymerase chain reaction (PCR) technology for simultaneous in vitro qualitative detection and differentiation of adenovirus (species B, C and E), common human coronaviruses (229E, HKU1, NL63, OC43), human metapneumovirus, human rhinovirus/enterovirus, influenza A virus, influenza B virus, parainfluenza viruses 1, 2, 3, and 4, respiratory syncytial virus (RSV), and SARS-CoV-2 in nasopharyngeal swab specimens obtained from individuals with signs and symptoms of respiratory tract infections in conjunction with clinical and epidemiological risk factors.

The detection and identification of specific viral nucleic acids from individuals presenting with signs and symptoms of a respiratory infection aids in the diagnosis of respiratory infection if used in conjunction with other clinical and epidemiological information. Negative results do not preclude a respiratory infection and should not be used as the sole basis for treatment or other patient management decisions. Conversely, positive results do not rule out coinfection with other organisms, and the agent detected may not be the definite cause of disease.

Due to the genetic similarity between human rhinovirus and enterovirus, the cobas® Respiratory flex test cannot reliably differentiate them.

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**	**Basic UDI-DI**
cobas® Respiratory flex	09623701190	IVR 0503	Class D	761333602992BX
cobas® Respiratory flex Control Kit	09623728190	IVR 0503	Class D	761333602992BX