Device Schedule:

Risk Classification: Class B near-patient devices

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Intended purpose** (as per the IFU)	**Basic UDI-DI**
cobas® Influenza A/B & RSV Nucleic acid test for use on the cobas® Liat® System	08160104190	IVR 0503	The cobas® Influenza A/B & RSV Nucleic acid test for use on the cobas® Liat® System (cobas® Influenza A/B & RSV) is an automated multiplex real-time RT-PCR assay for the rapid in vitro qualitative detection and discrimination of Influenza A virus, Influenza B virus and respiratory syncytial virus (RSV) RNA in nasopharyngeal swab specimens from patients with signs and symptoms of respiratory infection in conjunction with clinical and epidemiological risk factors. The test is intended for use as an aid in the differential diagnosis of Influenza A, Influenza B, and RSV in humans and is not intended to detect Influenza C. The cobas® Influenza A/B & RSV nucleic acid test for use on the cobas® Liat® System is intended for near patient testing and use by health professionals.	761333601252A9
cobas® Influenza A/B & RSV Quality Control Kit for use on the cobas® Liat® System	07402686190	IVR 0503	External Controls for use with the cobas® Influenza A/B & RSV nucleic acid test for use on the cobas® Liat® System (Part number 08160104190)	761333601251A7