Device Schedule:

Intended Purpose as per the Instructions for Use:

cobas® HIV-1 is an in vitro nucleic acid amplification test for the quantitation of human immunodeficiency virus type 1 (HIV-1) in EDTA plasma or from a **cobas®** Plasma Separation Card (PSC) dried plasma spot of HIV-1-infected individuals.

This test is intended for use in conjunction with clinical presentation and other laboratory markers for the clinical management of HIV-1-infected patients. This test can be used for confirmation of HIV-1 infection in antibody reactive individuals and to assess patient prognosis by measuring the baseline HIV-1 level or to monitor the effects of antiretroviral therapy by measuring changes in HIV-1 RNA levels during the course of antiretroviral treatment.

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**	**Basic UDI-DI**
cobas® HIV-1	09040803190	IVR 0504	Class D	761333600853B2