Device Schedule:

Intended Purpose as per the Instructions for Use:

cobas® HIV-1/HIV-2 Qualitative nucleic acid test for use on the **cobas**® 5800/6800/8800 Systems is an in vitro nucleic acid amplification test for the qualitative detection and differentiation of human immunodeficiency virus (HIV) type 1 (HIV-1) and type 2 (HIV-2) in human serum, plasma, and dried blood spots (DBS).

The test is intended to be used as an aid in diagnosis of HIV-1/HIV-2. Detection of HIV-1 or HIV-2 nucleic acid is indicative of HIV-1 or HIV-2 infection, respectively. The presence of HIV-1 or HIV-2 nucleic acid in the plasma or serum of individuals without antibodies to HIV-1 or HIV-2 is indicative of acute or primary infection. In infants born to HIV-infected mothers and who have maternal antibodies to HIV-1 or HIV-2, the presence of HIV nucleic acid is indicative of active infection. **cobas**® HIV-1/HIV-2 Qualitative may also be used to confirm HIV-1 or HIV-2 infection in an individual with specimens reactive for HIV-1 or HIV-2 antibodies or antigens.

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**	**Basic UDI-DI**
cobas® HIV-1/HIV-2 Qualitative	09040528190	IVR 0503	Class D	761333600856B8
cobas® HIV-1/HIV-2 Qualitative Control Kit	09040536190	IVR 0503	Class D	761333600869BH