Device Schedule:

Intended Purpose as per the Instructions for Use:

cobas® HCV is an in vitro nucleic acid amplification test for both the detection and quantitation of hepatitis C (HCV) RNA, genotypes 1 to 6, in human EDTA plasma or serum or from a **cobas®** Plasma Separation Card (PSC) dried plasma spot of HCV-infected individuals.

cobas® HCV is intended for use as an aid in the diagnosis of HCV infection in the following populations: individuals with antibody evidence of HCV with evidence of liver disease, individuals suspected to be actively infected with HCV antibody evidence, and individuals at risk for HCV infection with antibodies to HCV. Detection of HCV RNA indicates that the virus is replicating and therefore is evidence of active infection.

The test is intended for use in the management of patients with chronic HCV in conjunction with clinical and laboratory markers of infection. The test can be used to predict the probability of sustained virologic response (SVR) early during a course of antiviral therapy, and to assess viral response to antiviral treatment (response guided therapy) as measured by changes of HCV RNA levels in serum or EDTA plasma. The results must be interpreted within the context of all relevant clinical and laboratory findings. **cobas®** PSC dried plasma spots may be used in accordance with clinical practice guidelines and the assay's performance characteristics.

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**	**Basic UDI-DI**
cobas® HCV	09040765190	IVR 0504	Class D	761333600847B7