Device Schedule:

Intended Purpose as per the Instructions for Use:

The **cobas®** Zika test for use on the **cobas®** 5800/6800/8800 systems is a qualitative in vitro nucleic acid test for the direct detection of Zika virus RNA in human plasma.

This test is intended for use to screen donor samples for Zika virus RNA in plasma samples from individual human donors, including donors of whole blood and blood components, and other living donors. This test is also intended for use to screen organ and tissue donors when donor samples are obtained while the donors heart is still beating.

Plasma from all donors may be screened as individual samples. For donations of whole blood and blood components, plasma samples may be tested individually or in pools comprised of individual samples.

This test is not intended for use on samples of cord blood.

This test is not intended for use on cadaveric blood specimens.

The test may be used as an aid in diagnosis of Zika virus in samples collected from individuals suspected of infection with the Zika virus by their healthcare provider.

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**	**Basic UDI-DI**
cobas® Zika – 480	09040676190	IVR 0502	Class D	761333602118AB
cobas® Zika Control Kit	09040684190	IVR 0502	Class D	7613336021219Y