Device Schedule:

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Intended purpose** (as per the IFU)	**Risk Classification**	**Basic UDI-DI**
cobas® WNV - 480	09040927190	IVR 0502	The cobas® WNV test for use on cobas® 5800/6800/8800 systems is a qualitative in vitro test for the direct detection of West Nile Virus (WNV) RNA in human plasma. This test is intended for use to screen donor samples for WNV RNA in plasma samples from individual human donors, including donors of whole blood and blood components, as well as other living donors. This test is also intended for use to screen organ and tissue donors when donor samples are obtained while the donor's heart is still beating and for testing of cadaveric (non-heart beating) donors. This test is not intended for use on samples of cord blood. 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 may be tested in pools comprised of aliquots of individual samples. For donations from cadaveric (non-heart beating) organ and tissue donors, samples may only be screened as individual sample. This test may also be used as an aid in diagnosis of WNV in samples collected from individuals suspected of infection with WNV by their healthcare provider. When used as an aid in diagnosis, plasma samples should only be tested individually.	Class D	761333600866BB
cobas® WNV – 192	09171142190	IVR 0502		Class D	761333602494BA
cobas® WNV Control Kit	09040935190	IVR 0502		Class D	761333600867BD