Device Schedule:

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Intended purpose** (as per the IFU)	**Risk Classification**	**Basic UDI-DI**
cobas® Babesia - 480	09040692190	IVR0502	The cobas® Babesia test for use on the cobas® 5800/6800/8800 systems is a qualitative in vitro nucleic acid screening test for the direct detection of Babesia (B. microti, B, duncani, B. divergens, and B. venatorum) DNA and RNA in whole blood 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 donor's heart is still beating. Whole blood samples from all donors may be screened as individual samples or in pools comprised of aliquots of individual samples. This test may also be used as an aid in diagnosis of Babesia in samples collected from individuals suspected of Babesiosis by their healthcare provider. When used as an aid in diagnosis, whole blood samples should only be tested individually. This test is not intended for use on samples of cord blood. This test is not intended for use on cadaveric blood specimens.	Class D	761333602097AU
cobas® Babesia Control Kit	09040706190	IVR0502		Class D	7613336021209W