Device Schedule:

Intended Purpose as per the Instructions for Use:

The **cobas**® Malaria test for use on the **cobas**® 5800/6800/8800 systems (**cobas**® Malaria) is a qualitative in vitro nucleic acid screening test for the direct detection of *Plasmodium* (*P. falciparum, P. malariae, P. vivax, P. ovale* and *P. knowlesi)* DNA and RNA in whole blood samples from individual human donors, including donors of whole blood and blood components, as well as other living donors. It is also intended for use in testing whole blood samples to screen organ and tissue donors when samples are obtained while the donor's heart is still beating.

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

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

This test is not intended for use on cadaveric samples.

This test may also be used as an aid in diagnosis for Plasmodium infection in samples collected from individuals suspected of infection with Plasmodium parasite by their healthcare provider.

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**	**Basic UDI-DI**
cobas® Malaria -192	09352511190	IVR 0502	Class D	761333602917BH
cobas® Malaria Control Kit	09352520190	IVR 0502	Class D	761333602918BK