## Device Schedule:

| **Device Name** | **Model** | **Type** (Codes as per (EU) 2017/2185) | **Intended purpose** (as per the IFU) | **Risk Classification** | **Basic UDI-DI** |
|---|---|---|---|---|---|
| **cobas®** CHIKV/DENV - 480 | 09040650190 | IVR 0502 | The **cobas®** CHIKV/DENV for use on the **cobas®** 5800/6800/8800 systems is a qualitative in vitro test for the direct detection of chikungunya virus (CHIKV) RNA and dengue virus (DENV) serotypes 1-4 RNA in human plasma. The test is intended for use to screen donor samples for CHIKV RNA or DENV RNA alone or to simultaneously screen for both CHIKV and DENV RNA in plasma from individual human donors, including donors of whole blood, 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. Plasma from all donors may be screened as individual samples.<br>For donations of whole blood and blood components, plasma samples may be tested individually or plasma may be tested in pools comprised of aliquots of individual samples. This test is not intended for use of samples of cord blood. | Class D | 761333602365AW |
| **cobas®** CHIKV/DENV Control Kit | 09040668190 | IVR 0502 | | Class D | 761333602366AY |

| **Device Name** | **Model** | **Type** (Codes as per (EU) 2017/2185) | **Intended purpose** (as per the IFU) | **Risk Classification** | **Basic UDI-DI** |
|---|---|---|---|---|---|
| **cobas®** CHIKV/DENV Control Kit | 09040668190 | IVR 0502 | This test may be used as an aid in diagnosis for CHIKV or DENV in samples collected from individuals suspected of infection with chikungunya or dengue viruses by their healthcare provider.<br><br>When used as an aid in diagnosis, plasma samples should only be tested individually. | Class D | 761333602366AY |