

Statement of Compliance

15.203 & 15.204

Ventana Medical Systems (VMS) has a system bill of material (BOM) for the entire HE 600 system. One of the BOM line items is the antenna that is used with the RWF1 reader. The internal drawing for that antenna only permits the use of one component – no substitutions are permitted.

Furthermore, the use of external power amplifiers is not on the HE 600 BOM. Installation, maintenance and repair of the HE 600 system is to only be performed by VMS employees or their affiliates. All replacement materials are furnished by VMS, eliminating the chances of a non-approved antenna being used in the HE 600 system, or the inclusion of an external power amplifier.