Conditions of Acceptability - The following items are to be considered when evaluating the transformer and inductor in the end-use product.

1. An enclosure shall be provided for fire/electrical/mechanical protection for the transformer and inductor to prevent user contact with uninsulated live parts.

2. The transformer employs a Class 155 (F) insulation system.

3. The transformer complies with the construction requirements of ANSI/AAMI ES60601-1/(R)2012 and CAN/CSA 61010-1:14 3rd Edition. The dielectric tests were performed to verify isolation. Since the transformer was evaluated for construction only, all performance tests should be conducted in the end-use product.

4. The acceptability of the mounting means shall be determined in the final application.

5. 2 MOPP is provided between the primary and secondary windings based on the maximum working voltage of 240 Vrms.

6. 1 MOPP is provided between the primary and ground based upon a working voltage of 240 Vrms.

7. The transformers have been evaluated for indoor use only, maximum altitude 2000 m.

8. The transformer Shield 1 layer shall be reliably bonded to protective ground in the end-use product.

9. Overcurrent protection is to be connected to the ungrounded supply conductor of the transformers in the end use product. Overcurrent protection is to be rated in accordance with the ampacity of the wire leads of the ungrounded supply conductor.

10. Transformers to be placed in end-use equipment that employ means of disconnecting from the electrical supply source.

11. The acceptability of the length, routing, and AWG wire size of primary and secondary leads shall be determined in the final application.

12. Transformer employs previously certified, auto resettable thermal protector (YFZW2) rated 140 C.

13. Transformers subjected to earth and touch leakage current testing (8.7) for reference only.

14. Transformers have been subjected to Dielectric Strength Test of 8.8.3.

15. Transformers have been subjected to the Transformer Dielectric Strength Test of 15.5.2.

16. Clause 4.2, Risk Management was not evaluated. Risk Management to be conducted in the end product.