

Vivosmart Risk Assessment – Risk Assessment of Consumer Product Containing Lead

Vivosmart Risk Assessment – Risk Assessment of Consumer Product Containing Lead

Introduction

It has been determined that a supplier of a component for a consumer fitness product inadvertently used tin/lead solder rather than the EU RoHS low lead solder in soldering a connecting wire to the component. The lead content in the solder exceeds the RoHS threshold of 1000 mg/kg. This assessment outlines the exposure risks from the product.

Assessment

Observation #1

The non-RoHS solder is limited to the two solder connections used on an interior component contained within the product. The non-RoHS solder weighs less than 0.001g. The component is permanently mounted inside the product and does not come into physical contact with the user.







Observation #2

The solder connection is further sealed in place using a coating adhesive which covers the solder and wire connection. This adhesive, while intended to act as a bonding agent for the connection, also creates a barrier over the solder joint.



Observation #3

The component is physically sealed within the product and cannot be removed without breaking open the product. The product is permanently sealed so as to be rated as water resistant up to 50 meters. Garmin's Vivosmart passes a series of extensive shock, drop, pressure, torsion, pull, vibration, stress, and other physical tests to ensure the product maintains integrity during the wide range of physical activities and accidental impacts the unit will be subjected to by the users. The product is not intended to be opened by the user and would require excessive force to open the product which is sealed with a water-tight adhesive. Opening the product would essentially destroy it.





Conclusion

Due to the interior placement, physical construction and sealed installation of the component within the product, there is no risk of lead exposure to the user of the product during normal conditions of use.