# Project Descriptions

Problem Statement:

During an availability project in 2019, the TC connector on the CryoPLUS PCBA 191967 was updated at J6 from standard connector (Omega PCC-OST-T-100-ROHS) to a mini connector (Omega PCC-SMP-T-100-ROHS).

Even though the standard connector was Obsolete, and the design updated to the mini, the connectors at J5 and J6 were combined, and the standard and mini connectors left as approved components. This is causing non-conforming PCBAs to be received since the site can't use any with the standard connector. Requested Action: Previous BOM update mistake

# Product Family and Models Affected

CRYOPLUS Model: 7400, 7401, 7402, 7403, 7404, 7405, 7406, 7407

# Country(s)/Region(s) in scope

NA, Europe, APAC, LATAM,EMEA

# Regulatory status of the product

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| --- | --- | --- |
| S.No | Description | Applicability |
| 1.0 | Medical: | Yes |
| 1.1 | Countries of Registration: | Colombia, Vietnam, US FDA, Brazil,Malaysia,China |
| 1.2 | List the classification by country | IVIMA Colombia – Class II  MDA Malaysia – Class A  US FDA – Class II  ANVISA Brazil – Class II |
| 2.0 | Non-Medical | Yes |
| 3.0 | Certifications/markings on the units: | CE (Non-medical), UL |

# Regulatory Review Details

* **List Regulations/Directives/Standards affected by this change (if any)**