# 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

|  |  |  |
| --- | --- | --- |
| 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)**
  + **Regulations / Directives Applicable**
    - N/A
  + **Standards Applicable**
    - N/A
* **Documentation Requirements**
  + Design/Manufacturing/Quality
    - Remove PCC-OST-T-100-ROHS and add PCC-SMP-T-100 & PCC-SMP-T-50 as alternates for future use in BOM
  + Regulatory
    - These connectors are not listed in safety report E473332-D1040. Hence, UL files are not impacted and need not be updated
* **Testing Requirements**
  + Performance
    - FAI to be done
  + Regulatory
    - These connectors are not listed in safety report E473332-D1040. Hence, no testing deemed necessary
* **Any Specific Medical Device related requirement?**
  + N/A

# Regulatory / Agency Documents

|  |  |  |
| --- | --- | --- |
| Document Type | Report Number (if file update is applicable/ NA) | Status (Completed/In-progress) |
| Safety | NA | NA |
| EMC | NA | NA |
| Wireless | NA | NA |
| Medical Device Documents | NA | NA |

## Environmental Declarations

|  |  |  |
| --- | --- | --- |
| Document Type | Applicability(Yes/No) | Status(Received/To be provided) |
| ROHS | Yes | Yes |
| REACH | Yes | Yes |
| Prop65 | NA | NA |

## Agency Reporting for medical devices

* Did you inform regional RA about the design change?
  + - Yes
* If yes, enter the name of the regional RA
  + - Marlyn Barry -USA
    - Eduardo Pavonne – Brazil
    - Malaysia, Vietnam - Joanne

# Regulatory Affairs Recommendation

Based on the assessment provided, the proposed change is to update the BOM by removing the connector which is PCC-OST-T-100-ROHS. The proposed change does not impact the material and is only a BOM update.

Regulatory analysis indicates that there are no safety, EMC, or performance-related concerns associated with the proposed change. Although the part is not considered a critical component in the safety file, we need to document the environmental declarations for the newly added connectors for future use which are PCC-SMP-T-100 and PCC-SMP-T-50 (which is confirmed by the manufacturer to be same as the existing PCC-SMP-T-100-ROHS)

In summary, this change will not impact safety, EMC, or performance, and there is no change in the intended use of the product. Therefore, it is recommended that the regulatory can proceed with the implementation.

# Revision History

|  |  |  |  |
| --- | --- | --- | --- |
| **Revision Number** | **Phase Gate/Description of Change** | **Author** | **Revision Date** |
| 1.00 | Implement -L1 | Reshma Krishnan | 18 JUN 2024 |