INSTRUCTIONS FOR THE IDENTALLOY AND IDENTCERAM CERTIFICATE PROGRAMS APPLICATION

CONFIDENTIALITY PROVISION:

Information, materials, and samples submitted in conjunction with the application will be held in confidence. To the extent an applicant's information must be brought to the Board for consideration, the reviewer will redact confidential information and only release the necessary information related to the issue for Board review.

ENTITY INFORMATION:

- GUDID ID Number means, if applicable, listing the entity's Global Unique Device Identification Database identification number.
- FDA Registration Number means the information listed in the entity's profile found in the FDA's Establishment Registration & Device (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm)
- All provided entity information should match with the information registered with the FDA Registration Database.
- If the entity functions as a Relabeler/Private Label Distributor (PLD) then the contracted with manufacturer information is required. Please note the contracted manufacturer section ONLY applies to Relabeler/PLD entities.
- Within the Relabeler/PLD contract manufacturer identification section the Applicable 510(k) section requires the listing of each 510(k) identifier for the materials being certified under the program

QUESTIONS:

- Please list either "Y" (for yes) or "N" (for no) in response to each question.
- Entity is expected to provide an explanation for any "yes" response to questions 3 – 6 in the application. Please submit a separate document containing the offered explanations.
- The reviewers reserve the right to contact the entity with follow up questions as needed. If necessary, the reviewer will reach out to the listed entity via the contact information provided on the application.
- The scope of this section relates to the applying entity only.

ATTESTATION:

- Only initial next to statements applicable the entity's registered status. As an example, a repackager would not initial next to the statement "I attest that this entity operates as an FDA registered manufacturer in the United States".

REQUIRED ATTACHMENTS:

- Images of product labeling and branding should be limited to the entity's 510(k)s. The application does NOT require labeling and branding for every iteration of a product that aligns with one 510(k). Please provide one example for each 510(k), and the brand name must appear in the provided images.

All questions regarding the application may be submitted via email to info@identalloy.org.