APPLICATION FOR THE IDENTALLOY AND IDENTCERAM CERTIFICATE PROGRAMS

ENTITY INFORMATION:

Applying for: ☐ IdentAlloy ☐ IdentCeram ☐ Both

Application Completed by:

Name: _____ Title/Job Description: _____

Entity Name (including DBA): _____

FDA Registration Number:_____

Phone: _____ Email: _____

Address: _____

Website URL: _____

Number of Locations: _____ Number of Employees: _____

Business Origin Date: _____ GUDID ID No.:_____

Please select the following categories applicable to the applying entity. FDA registration should match the categories selected below:

Domestic _____ Foreign_____

Manufacturer:_____ Repackager:_____ Relabeler*:_____

*If functioning as a relabeler, i.e. Private Label Distributor (PLD), please list the following information:

Entity Name (including DBA):_____

FDA Registration Number: _____

Applicable 510(k)s:_____

Please list entity's United States Agent: (if more than one U.S. Agent please attach a separate document listing each individual's name, telephone number, email, and address).

Name: _____ Telephone: _____

Email: _____ Address: _____

REFERENCES:

The IdentAlloy and IdentCeram Certificate Programs require two references from currently program-certified entities. Specifically, reference contact information for a program-certified manufacturer and laboratory.

(1) Manufacturer

Name:

_____

Telephone Number: _____

(2) Laboratory

Name: _____

Telephone Number: _____

QUESTIONS:

Please list either Y (for "yes") or N (for "no") in response to each question below.

1. _____ The entity holds appropriate FDA documentation for the entity's registration and sale of patient contact materials, including but not limited to registration as a United States Distributor, as applicable.
2. _____ Does the entity possess policies for ensuring compliance with FDA regulatory requirements, including Quality System Regulations and current Good Manufacturing Practices (cGMP)?
3. _____ Has the entity reported any adverse events to the FDA in the past 5 years? If so, then please describe and provide status of same.
4. _____ In the past 5 years, has the entity received or been made aware of any complaints regarding any materials, including but not limited to reactions and/or illness? If so, then please describe and provide status of same.
5. _____ Has the entity been subject to any actual or threatened regulatory enforcement by any government entity, including (but not limited to) the FDA, state or local regulators? If so, then please describe and provide status of same.
6. _____ Have any lawsuits alleging injuries related to entity materials, issues with quality control, and/or failure to comply with regulatory requirements been brought against the entity in the last 5 years? If so, then please describe and provide status of same.

ATTESTATIONS: (initial next to each applicable statement)

_____ I attest that the classification and content of alloys or ceramic materials used in entity's materials meet American Dental Association Standards.

_____ I attest that this entity has created and implemented a Quality Management System pursuant to the FDA's QSR/ current Good Manufacturing Practices, as applicable.

_____ I attest that this entity possesses all policies and procedures as required by American Dental Association Standards.

_____ I attest that this entity operates as an FDA registered manufacturer in the United States.

_____ I attest that this entity, or its distributor, operates as an FDA registered reseller in the United States.

REQUIRED ATTACHMENTS:

- Images of product labeling and branding. (See Instructions)
- Certificate of Corporation or Articles of Organization from applicable Secretary of State.
- Copies of 3rd party issuance of proof of current CE Mark and ISO certification as applicable.
- SDS, safety data sheets, for product materials.
- Additional documentation may be attached to answer any of the above questions.

PROCESS:

Your entity will be placed in the review period once this document is completed in full (including any supportative documentation) and submitted. All information included on this application remains confidential, subject to reviewer discretion. The IdentAlloy and IdentCeram Certificate Programs will strive to conduct your application review as soon as possible.

ANNUAL NOTICE REQURIEMENT:

Within five (5) business days of the entity's annual FDA registration renewal, the entity will submit to the IdentAlloy and IdentCeram Certificate Programs proof that FDA registration is in good standing for the federal government's current fiscal year. Proof of submission and approval may be submitted via email info@identalloy.org or by mail at IdentAlloy Council, 325 John Knox Rd., Ste. L103, Tallahassee, FL 32303.

PLEASE NOTE: YOUR ENTITY MUST ALWAYS BE IN COMPLIANCE WITH ALL AMERICAN DENTAL ASSOCIATION STANDARDS AND APPLICABLE FDA REQUIREMENTS AND YOUR ENTITY MUST NOTIFY THE IDENTALLOY AND/OR IDENTCERAM PROGRAMS, AS APPLICABLE, WITHIN FIVE (5) BUSINESS DAYS OF RECEIVING ANY NOTICE INDICATING SUCH NON-COMPLIANCE.*

I, having the authority to represent this entity, verify that _____ (entity's legal name) has met the above requirements for certification. If this entity fails to meet any of the aforementioned requirements at any point, certification will be revoked.

_____
Print Name

_____
Title

_____
Date

_____
Signature