



K2M, INC

Required Purchasing Codes

Code	Description
A	Production Parts
A1	Production Parts w/ no Material Certificate, Contract Services
B	Calibration Services
C	Cleaning of Implants
D	Testing Services
AC	Combination of both Codes A and C

Code A:

All shipments must be accompanied with:

Material Certifications (including Heat Treat Certification when applicable), Packing List and Certificate of Conformance. By submitting a signed Certificate of Conformance, the supplier has agreed when applicable to have met all the stated requirements on the print, including but not limited to: dimensional physical, material, cleaning, visual, sterilization, passivation, anodizing, etc. All supplier procedures that differ from the stated K2M, Inc., procedure must be approved by K2M, inc., prior to use. No material certificates will be required for K2M, Inc. supplied material.

Code A1:

All shipments must be accompanied with:

Packing List and Certificate of Conformance. By submitting a signed Certificate of Conformance the supplier has agreed to have met all the stated requirements on the print, including but not limited to: dimensional, physical, material, cleaning, visual, passivation and/or anodizing (when required), etc. All supplier procedures that differ from the stated K2M, Inc., procedure must be approved by K2M, Inc., prior to use.

Code B:

K2M, Inc., requires that any calibration services purchased from an outside vendor will require traceability to NIST or other recognized standard and the immediate notification upon finding any items serviced to be out of tolerance. A long form certificate is required for all requested calibration services. These requirements are based upon the efforts of K2M, Inc. to be in full compliance of ISO standards.
(Reference ISO 13485: 2003, Clause 7.4.2, and 7.6 (a)).

Code C:

K2M, Inc., requires that suppliers notify K2M, Inc., of any changes to their cleaning procedures

Code D:

K2M, Inc., requires that suppliers providing testing services (i.e. sterility, biomechanical, bioburden, etc.) supply a test report. The documentation will be used to determine whether results are within the acceptance criteria.

Code AC:

This code denotes that both code A and code C apply. Whenever two or more codes are combined the service provider must comply with all codes.