

**American
National
Standard**

ANSI/AAMI/ISO 13488:1996

**Quality systems—Medical
devices—Particular
requirements for the application
of ISO 9002**

Quality systems—Medical devices— Particular requirements for the application of ISO 9002

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Committee Representation

Association for the Advancement of Medical Instrumentation Committee on Quality Management and Corresponding General Aspects for Medical Devices

The adoption of ISO 13488:1996 as an American National Standard was initiated by the AAMI Committee on Quality Management and Corresponding General Aspects for Medical Devices, which also serves as a U.S. Technical Advisory Group (TAG) to the relevant work in the International Organization for Standardization (ISO). U.S. representatives from the AAMI Application of Quality Systems to Medical Devices Working Group (U.S. Sub-TAG for ISO/TC 210/WG 1) played an active role in developing the ISO standard, and AAMI working group cochair Mr. Edward Kimmelman also serves as convener of ISO/TC 210/WG 1.

The **AAMI Committee on Quality Management and Corresponding General Aspects for Medical Devices** has the following members:

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