



August 26, 2009

**CERTIFICATION STATEMENT**

In my capacity as Director, International Regulatory Affairs, Carestream Health, Inc., I certify that the ISO 13485:2003 certification is the appropriate quality management system for manufacturers of medical devices.

This statement is to clarify why Carestream Health, Inc. maintains certification to ISO 13485:2003 and not ISO 9001:2000 for the facilities where Class II and higher, and most Class I, medical devices are designed and manufactured.

ISO 13485:2003, "Medical devices - Quality management systems -Requirements for regulatory purposes" provides a set of quality management system requirements very similar to ISO 9001:2000 but is very specific to organizations that design, manufacture, install or service medical devices; that is, manufacturers of medical devices.

EN ISO 13485:2003 is the EU harmonized standard for quality management systems related to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. It provides a good base model for compliance with the EU CE marking Medical Devices Directives (Annex II, V, VI).

Prior to the year 2003, the EU harmonized standard for medical device quality systems (EN ISO 13485:2000) was based on the ISO 9001:1994 standard. When ISO 9001 was revised in the year 2000, many of the specific requirements for documentation and records were removed, and it was no longer viewed as acceptable for regulatory purposes for facilities that manufacture Class II or higher devices within the medical device industry. Therefore, in 2003, ISO 13485 was revised to be independent of ISO 9001, and it retained the specificity needed to assure medical device manufacturers continue to deliver devices that are safe and effective. ISO 13485:2003 is the international standard recognized for medical device Quality Management Systems registration.

For these reasons, Carestream Health maintains certification to ISO 13485:2003 for facilities that manufacture Class II or higher devices and, although not mandated to support Council Directive 93/42/EEC, also elects to maintain it for most Class I facilities. This position is aligned with the guidance provided by BSI, Carestream Health's certifying body, and also its notified body for the European Union. There is no additional value to be realized by maintaining both ISO 13485 and ISO 9001 certification.

A handwritten signature in black ink, appearing to read "Robert C. Meagher".

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