

Varian Medical Systems X-ray Products

Registration and Certifications Index

Varian Medical Systems X-Ray Products is currently registered or certified under the following regulations and standards:

- ISO 13485
- Varian holds an EC certificate under the requirements of Council Directive 93/42/EEC
- Canadian Medical Device Regulation, P.C.
- ISO 9001
- UL/IEC 60601-1
- CSA 22.2 No. 601.1
- Chinese SFDA Registration Nos. 0712278, 0714670, 0004482
- Japanese PAL/Yakuji-Ho: Controlled MD
- Russian MHSD: Federal Law No. 184-FZ

Salt Lake City, UT

- FDA 21 CFR, Sub-Chapter J. Initial report number 7410266
- ISO 9001 Certificate Number FM21804
- ISO 13485 Certificate Number FM77566
- CE Mark Certificate Number CE 00999
- Canadian Medical Device Regulations (CMDCAS)

Charleston, SC

- FDA 21 CFR, Sub-Chapter J. Initial report number 8612039
- ISO 9001 Certificate Number FM81645
- ISO 13485 Certificate Number FM84906
- CE Mark Certificate Number CE 00999

Willich, Germany

- ISO 13485 Certificate Number FM84906
- CE Mark Certificate Number CE 00999

Beijing, China

- YY/T 0287 Certificate No. 04709Q10016ROS-1
- Beijing Hua Guang Certification of Medical Devices Co. Ltd. (CMD)

Varian X-Ray Products complies with requirements of:

- WEEE (Waste Electrical and Electronic Equipment) Directive 2002/96/EC
- RoHS (Reduction of Hazardous Substances) Directive 2002/95/EC
- Administrative Measure on the Control of Pollution Caused by Electronic Information Products, No. 39 (28 February 2006 – People's Republic of China) SJ/T11364-2006