



## Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Siemens Medical Solutions USA, Inc. Molecular Imaging

2501 N. Barrington Road Hoffman Estates

Illinois 60192

USA

**Holds Certificate No:** 

FM 91063

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, Development, Manufacture, Service and Distribution of Molecular Imaging Systems including Clinical PET, PET/CT, SPECT, and SPECT/CT Systems; Preclinical PET, Preclinical CT and Preclinical Multi-Modality Systems; Cyclotrons; Radioactive Sources; Chemistry Modules; Associated Software. Computer Workstations and related Accessories.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

(Jany @ Shade

Original Registration Date: 2004-12-03

Latest Revision Date: 2021-06-01





Effective Date: 2021-06-06 Expiry Date: 2024-06-05

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To be read in conjunction with the scope above or the attached appendix.

Certificate No:

FM 91063

Location		Registered Activities
Siemens Medical Solutions USA, Molecular Imaging 2501 N. Barrington Road Hoffman Estates Illinois 60192 USA	Inc.	Design, Development, Manufacture, Service and Distribution of Molecular Imaging Systems including Clinical PET, PET/CT, SPECT, and SPECT/CT Systems; Preclinical PET, Preclinical CT and Preclinical Multi-Modality Systems; Cyclotrons; Radioactive Sources; Chemistry Modules; Associated Software, Computer Workstations and related Accessories.
Siemens Medical Solutions USA, Molecular Imaging 810 Innovation Drive Knoxville Tennessee 37932 USA	Inc.	Design and Development of Clinical PET, PET/CT, Cyclotrons, Radioactive Sources, Chemistry Modules; Associated Software, Computer Workstations and related Accessories. Manufacture and Distribution of Radioactive Sources and Chemistry Modules Service of Clinical PET, PET/CT, Preclinical PET, Preclinical CT and Preclinical Multi-Modality Systems; Cyclotrons, Radioactive Sources, Chemistry Modules; Associated Software, Computer Workstations and related Accessories.
Siemens Medical Solutions USA, Molecular Imaging 203 Dunavant Drive Rockford Tennessee 37853-3065 USA	Inc.	Design and Development of Components for Clinical PET, PET/CT.
Siemens Medical Solutions USA, Molecular Imaging 207 Dunavant Drive Rockford Tennessee 37853-3065 USA	Inc.	Manufacture of Components for Clinical PET, PET/CT.
Siemens Medical Solutions USA, Molecular Imaging 3100 Stockcreek Blvd. Rockford Tennessee 37853-3052 USA	Inc.	Manufacture of Components for Clinical PET, PET/CT.
Original Registration Date: 2004 Latest Revision Date: 2021-06-0	l .	Effective Date: 2021-06-06 Expiry Date: 2024-06-05

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Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA A Member of the BSI Group of Companies.







## Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Siemens Medical Solutions USA, Inc.

Molecular Imaging 2501 N. Barrington Road

Hoffman Estates

Illinois 60192 USA

**Holds Certificate No:** 

FM 509812

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

Design, Development, Manufacture, Service and Distribution of Molecular Imaging Systems including Clinical PET, PET/CT, SPECT, and SPECT/CT Systems; Preclinical PET, Preclinical CT and Preclinical Multi-Modality Systems; Cyclotrons; Radioactive Sources; Chemistry Modules; Associated Software. Computer Workstations and related Accessories.

For and on behalf of BSI:

Carlos Pitanga, Chief Operating Officer Assurance – Americas

Original Registration Date: 2006-07-15 Latest Revision Date: 2021-06-01

Effective Date: 2021-06-06 Expiry Date: 2024-06-05

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Certificate No: FM 509812

Location	Re	egistered Activities
Siemens Medical Solutions USA, Molecular Imaging 2501 N. Barrington Road Hoffman Estates Illinois 60192 USA	of SP an Ra	Pesign, Development, Manufacture, Service and Distribution of Molecular Imaging Systems including Clinical PET, PET/CT, PECT, and SPECT/CT Systems; Preclinical PET, Preclinical CT and Preclinical Multi-Modality Systems; Cyclotrons; adioactive Sources; Chemistry Modules; Associated oftware, Computer Workstations and related Accessories.
Siemens Medical Solutions USA, Molecular Imaging 810 Innovation Drive Knoxville Tennessee 37932 USA	of pro sy as	resign, development, manufacture, service and distribution f molecular imaging systems including clinical PET, PET/CT, reclinical PET, preclinical CT and preclinical multi-modality systems; cyclotrons, radioactive sources, chemistry modules; ssociated software, computer workstations and related ccessories.
Siemens Medical Solutions USA, Molecular Imaging 203 Dunavant Drive Rockford Tennessee 37853-3065 USA		esign, Development of Molecular Imaging Systems including linical PET, PET/CT.
Siemens Medical Solutions USA, Molecular Imaging 207 Dunavant Drive Rockford Tennessee 37853-3065 USA		lanufacture of molecular imaging systems including clinical ET, PET/CT.
Siemens Medical Solutions USA, Molecular Imaging 3100 Stockcreek Blvd. Rockford Tennessee 37853-3052 USA		lanufacture of molecular imaging systems including clinical ET, PET/CT.
Original Registration Date: 2006 Latest Revision Date: 2021-06-0	1	Effective Date: 2021-06-06 Expiry Date: 2024-06-05

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
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