

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 2214580-1

Certificate Holder: GE Medical Systems Information
Technologies, Inc.
3114 N Grandview Blvd
Waukesha, WI 53188
USA

Scope: Design and Development, Manufacture, Distribution,
Installation and Service of Patient monitoring systems,
Cardiology ECG recording and Analysis systems, Invasive
cardiology equipment systems, Medical Analysis Software and
Blood Pressure Cuffs.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 234205801-11

Effective date: 2023-12-18

Expiry date: 2026-04-03

Issue date: 2023-12-18

Replaces certificate SX 2214580-1 issued on 2023-04-04

This certificate can be validated on <https://www.certipedia.com>



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Tillystraße 2 · 90431 Nürnberg · Germany

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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	GE Medical Systems Information Technologies, Inc. 3114 N Grandview Blvd Waukesha, WI 53188 USA	Design and Development, Manufacture, Distribution, Installation and Service of Patient monitoring systems, Cardiology ECG recording and Analysis systems, Invasive cardiology equipment systems, Medical Analysis Software and Blood Pressure Cuffs.
/02	GE Medical Systems Information Technologies, Inc. 9900 Innovation Drive Wauwatosa, WI 53226 USA	Design and Development, Manufacture, Distribution, Installation and Service of Patient monitoring systems, Cardiology ECG recording and Analysis systems, Invasive cardiology equipment systems, Medical Analysis Software and Blood Pressure Cuffs.

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