# EC Certificate

**EU Quality Management System**
**REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III**

TÜVRheinland®

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| Registration No.: | HZ 2214580-1 |
| Manufacturer: | **GE Medical Systems Information Technologies, Inc.**<br>9900 Innovation Drive<br>Wauwatosa, WI 53226<br>USA |
| EUDAMED Single Registration No.: | N/A |
| Products: | Class IIa- Z120503 ELECTROCARDIOGRAPHS<br>Class IIb -Z120302 VITAL SIGNS MONITORING INSTRUMENTS |
| Authorised representative(s): | **GE Medical Systems SCS**<br>283 Rue de la Miniere, 78530 BUC<br>France |

| Certificate history | | |
|---|---|---|
| Revision: | Description: | Issue date: |
| 0 | Initial | 2020-11-17 |

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

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| Report No.: | 234158038-30 |
| Effective date: | 2020-11-17 |
| Expiry date: | 2025-10-30 |
| Issue date: | 2020-11-17 |

TÜV Rheinland Product Safety GmbH Zertifizierungsstelle TÜVRheinland®

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
BS-MDR-091

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TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.



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