

The management system of  
**SAMSUNG ELECTRONICS  
CO., LTD.**

129, Samsung-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do, Korea



has been assessed and certified as meeting the requirements of

**ISO 13485:2016  
EN ISO 13485:2016**

For the following activities

**The scope of registration appears on page 2 of this certificate.**

This certificate is valid from 20 February 2018 until 20 February 2021  
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 11 February 2021

Issue 13. Certified since 20 February 2012

Authorised by

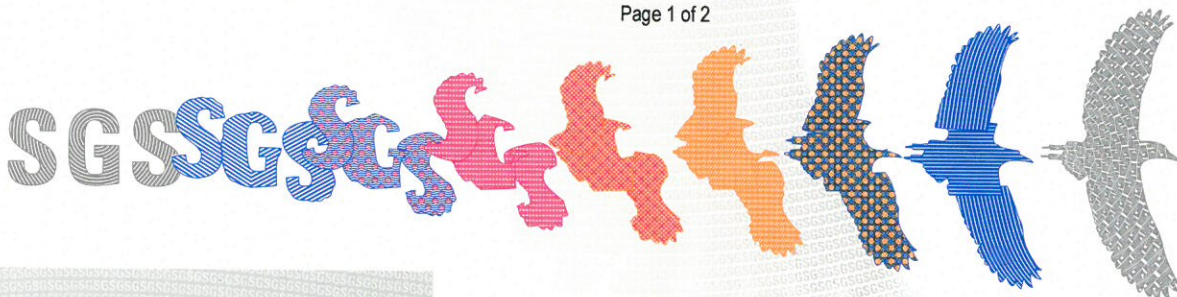


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# SAMSUNG ELECTRONICS CO., LTD.

## ISO 13485:2016 EN ISO 13485:2016



Issue 13

Detailed scope

**Design, Development, Manufacture, Installation and Distribution of Diagnostic X-ray system and Retrofit Kit for Digital Radiography**  
**Design, Development, Manufacture, Distribution and Service of in-vitro diagnostic analyzers/software, in-vitro diagnostic reagents, in-vitro diagnostic test kits used in the monitoring, management, detection of clinical chemistry, hematology and immunology**  
**Design, Development and Manufacture of Mobile Digital Batteries X-ray units**



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