

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Varex Imaging Equipment (China)
Co., Ltd.
Building G Plainvim international Park
No. 30 Wanquan Road
Xishan District
Wuxi
Jiangsu
214101
China

Facility ID Number: F006658

Holds Certificate No:

MDSAP 786307

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

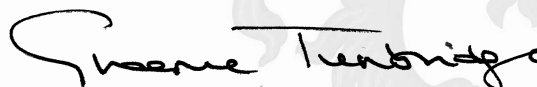
Canada: Medical Devices Regulations - Part 1 - SOR 98/282

Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

The manufacture and service of X-ray flat panel detectors. The manufacture, distribution and service of medical X-ray generating tube products.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2023-08-09

Effective Date: 2023-08-09

Expiry Date: 2026-08-08



BSI Group America Inc. is an MDSAP recognised auditing organization

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