

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Varex Imaging Equipment (China)
Co., Ltd.
Building G, Plainvim International
Industry 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:

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

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 contract manufacture and servicing of X-ray flat panel detectors.

The contract manufacture, distribution and servicing of medical Xray generating tube assemblies.

For and on behalf of BSI:


Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2023-08-09

Effective Date: 2026-08-09

Expiry Date: 2029-08-08



BSI Group America Inc. is an MDSAP recognised auditing organization

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