By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 824229 R000

Manufacturer: Varex Imaging Corporation

Address:
1678 South Pioneer Road
Salt Lake City
Utah
84104
USA

Single Registration Number: US-MF-000028124

EU Authorised Representative: Arazy Group GmbH

Address:
Am Flughafen
The Squaire 12
Frankfurt am Main
60549
Germany

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2025-04-29**

Current Issue Date: **2025-04-29**

Starting Validity Date: **2025-04-29**

Expiry Date: **2029-12-08**

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Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
Nexus DR	The Varex Nexus DR Digital X-ray Imaging System enables an operator to acquire, display, process, and export medical x-ray images for long-term storage. The Varex Nexus DR Digital X-ray Imaging System is intended for use in general radiographic examinations and applications (excluding fluoroscopy, angiography, and mammography).
Nexus DRF	The Varex Nexus DRF Digital X-Ray Imaging System enables an operator or to acquire, display, process, and export combined medical x-ray / fluoroscopy images for long-term storage. The Varex Nexus DRF Digital X-ray Imaging System is intended for use in general radiographic examinations and applications (excluding mammography).

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	30382286	Issued

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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