

# EU Quality Management System Certificate

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

## MDR 759430 R000

**Manufacturer:** Varex Imaging Group Nederland B.V.

**Address:**

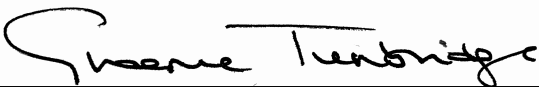
Fabriekstraat 41  
DOETINCHEM  
7005 AP  
The Netherlands

**Single Registration Number:** NL-MF-000002153

**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: **2024-10-04**

Current Issue Date: **2024-10-04**

Starting Validity Date: **2024-10-04**

Expiry Date: **2029-10-03**

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### Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
Optica 10 series	The Optica 10 series are manual X-ray collimators. A collimator is intended to restrict the dimensions of a diagnostic X-ray field by limiting the size of the primary X-ray beam.
Optica 20 series	The Optica 20 series are manual X-ray collimators. A collimator is intended to restrict the dimensions of a diagnostic X-ray field by limiting the size of the primary X-ray beam.
Optica 30/40/50 series	The Optica 30/40/50 series are motorized X-ray collimators. A collimator is intended to restrict the dimensions of a diagnostic X-ray field by limiting the size of the primary X-ray beam.
SolidStateMC series	The SolidstateMC series are accessories to X-ray systems used to measure the dose rate of X-rays by converting X-ray photon energy into an electrical current intended for AEC, which is proportional to the X-ray dose or dose rate.
Ionization Chamber series	The Ionization Chamber series are accessories to X-ray systems used to measure the dose rate of X-rays by converting X-ray photon energy into an electrical signal intended for AEC, which is proportional to the X-ray dose or dose rate.

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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	3556607	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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Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.  
A Member of the BSI Group of Companies.