EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 00999**

Issued To: **Varex Imaging Corporation**
1678 South Pioneer Road
Salt Lake City
Utah
84104
USA

In respect of:

The design and manufacture of diagnostic X-Ray tubes, CT tubes and mammography tubes, and the design and manufacture of flat panel imaging components and systems.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

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

Gary E Slack, Senior Vice President - Medical Devices

First Issued: **1995-11-15** Date: **2020-01-22** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 00999

Issued To:

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NBOG Code	Device description	Intended purpose per IFU
Class IIb		
MD 1201	Diagnostic X-Ray Tubes	Intended to be used in Radiography.
MD 1201	CT Tubes	Intended to be used in Computed Tomography.
MD 1201	Mammography Tubes	Intended to be used in Mammography.
Class IIa		
MD 1201 MDS 7010	Flat Panel Imaging components – Radiography panels	Intended to be integrated into products by X-ray manufacturers for radiographic applications.
MD 1201 MDS 7010	Flat Panel Imaging components – Fluoroscopic panels	Intended to be integrated into products by X-ray manufacturers for fluoroscopic applications.

First Issued: **1995-11-15** Date: **2020-01-22** Expiry Date: **2024-05-26**

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By Royal Charter

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 00999**

Date: **2020-01-22**

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Date	Reference Number	Action
15 November 1995	-	First Issue.
17 September 1996	-	Addition of 'refurbishment' to the scope.
05 August 1998	-	Addition of sub-contractor 'VARIAN INTERAY' for 'The full refurbishment of X-ray tubes and the design and manufacture of amorphous-silicon flat panel imaging systems'.
26 January 2000	-	Addition of 'the design, development and manufacture of amorphous silicon flat panel imaging systems' to the scope.
23 February 2005	4660194	Certificate renewal. Scope update to improve regulatory compliance.
30 November 2005	4778102	Addition of Varian Medical Systems Deutschland GmbH (Germany) as a subcontractor.
11 December 2007	7145590	Clarification of scope, the activity refurbishment has been removed as it was misleading. The company will continue to fit replacement x-ray tubes in a previously manufactured tube housing assemblies Clarification of scope to specifically detail the components of amorphous silicon flat panel imaging systems.

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Date	Reference Number	Action
20 January 2010	7474386	Addition of VMS UK Ltd to significant subcontractor list as authorised representative. Certificate renewal.
13 April 2010	7506821	Addition of Varian Medical Systems X-Ray Products, California, as a design subcontractor.
09 May 2012	7819479	Company name changed from Varian Medical Systems to Varian Medical Systems, Inc. Design services moved from Varian Medical Systems, X-Ray Products, 2599 Garcia Avenue, Mountain View, CA 94043, USA to Varian Medical Systems Inc., X-Ray Products, 3120 Hansen Way- Bldg 4 M/S G-103, Palo Alto, CA 94043, USA.
23 January 2015	8253504	Certificate Renewal.

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Date	Reference Number	Action
02 June 2015	8347872	Removal of the last four digits of the postal zip code from the legal manufacturer's address to match other certificates.
04 January 2017	8652652	Change of legal manufacturer name from Varian Medical Systems Inc to Varex Imaging Corporation. Removal of VMS UK Ltd and Varian Medical Systems, Inc – CA 94043 from the sub-contractors list and addition of Claymount. Change of name From Varian Medical Systems to Varex Imaging on the remaining subcontractors.
01 February 2018	8867468	Addition of Varex Imaging Equipment (China) as a Manufacture Sub-contractor.
24 March 2019	8940261	Change of EU Authorised Representative from Claymount to Arazy Group GmbH, Am Kalkhofen 8, Wöllstadt, 61206, Germany. Extension to scope, by removing 'amorphous-silicon'. Change of address of subcontractor Varex Imaging Deutschland AG, to Otto-Brenner-Str. 10, D 47877 Willich, Germany, following verification visit.
25 March 2019	8939261	Traceable to NB 0086.

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Date	Reference Number	Action
22 January 2020	9774581	Certificate renewal. EU Rep address changed from 'Am Kalkhofen 8, Wöllstadt, 61206, Germany' to 'Am Flughafen, The Squaire 12, 60549 Frankfurt am Main, Germany'. Product table added to certificate. Correction of typographical error in the address of subcontractor Varex Imaging (China).
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
25 June 2021	3478796	Removed subcontractor "Varex Imaging Corporation, 3235 Fortune Drive, North Charleston, South Carolina, 29418 USA"
28 August 2024	30207540	Addition of subcontractor. Removal of subcontractor page.

Inspiring trust for a more resilient world.

28 August 2024

Varex Imaging Corporation
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To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	**Directive and Annex**	**Reference Number**	**Changes approved**
CE 00999	93/42/EEC Annex II excluding Section 4	30207540	Addition of subcontractor. Removal of subcontractor page.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices

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SUSTAINABLE DEVELOPMENT GOALS

Varex Imaging Corporation
1678 South Pioneer Road
Salt Lake City
Utah
84104
USA

21 Dec 2023

Notified Body Confirmation Letter

Reference: EU2023-607/ 751911

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Varex Imaging Corporation
1678 South Pioneer Road
Salt Lake City
Utah
84104
USA

SRN Number (if available): US-MF-000028124

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR

application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
XRayTubeRADSN **0854344007**	Class IIb excluding Class IIb implantable non-WET	N/A	CE 00999; NB Number: 2797
XRayTubeCTGL **0854344007**	Class IIb excluding Class IIb implantable non-WET	N/A	CE 00999; NB Number: 2797
XRayTubeMAMMOBH **0854344007**	Class IIb excluding Class IIb implantable non-WET	N/A	CE 00999; NB Number: 2797
Img_ReceptorSJM **0854344007**	Class IIa	N/A	CE 00999; NB Number: 2797
Img_ReceptorPJF **0854344007**	Class IIa	N/A	CE 00999; NB Number: 2797

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2023/12/21	Initial issue