By Royal Charter

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

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 00999**
Date:	**2020-01-22**
Issued To:	**Varex Imaging Corporation** **1678 South Pioneer Road** **Salt Lake City** **Utah** **84104** **USA**

Subcontractor:	**Service(s) supplied**
Arazy Group GmbH Am Flughafen The Squaire 12 Frankfurt am Main 60549 Germany	**EU Representative**
Varex Imaging Deutschland AG Otto-Brenner-Str. 10 Willich D 47877 Germany	**Manufacture**
Varex Imaging Equipment (China) Co., Ltd. Building G Plainvim International Park No. 30 Wanquan Road Xishan District Wuxi Jiangsu 214101 China	**Manufacture**

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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"

Inspiring trust for a more resilient world.

25th June 2021

Varex Imaging Corporation
1678 South Pioneer Road
Salt Lake City
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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	3478796	Removed subcontractor "Varex Imaging Corporation, 3235 Fortune Drive, North Charleston, South Carolina, 29418 USA"

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,

Gary Slack
Senior Vice President, Medical Devices

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