



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 amorphous silicon 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 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **15 November 1995**

Date: **04 January 2017**

Expiry Date: **27 January 2020**

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Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.



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EC Certificate - Full Quality Assurance System

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: **04 January 2017**
Issued To: **Varex Imaging Corporation**
1678 South Pioneer Road
Salt Lake City
Utah
84104
USA

Subcontractor:	Service(s) supplied
Claymount Assemblies B.V. Anholtseweg 44, 7091 HB Dinxperlo P.O. Box 44, 7090 AA Dinxperlo Netherlands	EU Representative
Varex Imaging Corporation 3235 Fortune Drive North Charleston South Carolina 29418 USA	Manufacture
Varex Imaging Deutschland AG Karl-Arnold Strasse 12 D 47877 Willich Germany	Manufacture

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EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: CE 00999
 Date: 04 January 2017
 Issued To: Varex Imaging Corporation
 1678 South Pioneer Road
 Salt Lake City
 Utah
 84104
 USA

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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Page 1 of 2

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EC Certificate - Full Quality Assurance System

Certificate History

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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
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.

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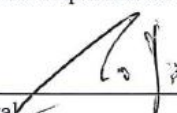
CE Declaration of Conformity



We:	EC Representative:
Varex Imaging Corporation 1678 S. Pioneer Road Salt Lake City, UT 84104	Claymount Assemblies B.V. Anholtseweg 44, 7091 HB Dinxperlo P.O. Box 44, 7090 AA Dinxperlo The Netherlands

Models:	Refer to Varex X-Ray Tube Model List on pages 2 through 4 of this document
Directives:	MDD: Directive 93/42/EEC, 2007/47/EC, Annex II, Section 3.2 RoHS: Directive 2011/65/EU
Notified Body:	BSI, Notified Body Number 0086
Classification:	Class IIb (Annex IX 3.2, Rule 10)
Applicable Standards:	EN/IEC 60601-1: 2006/2005 (3rd Edition) EN 60522:1999 EN 60601-1-3:2008 EN 60601-2-28:2010 IEC 60336:2005 IEC 60526:1978 IEC 60613:2010 EN ISO 13485:2012 EN 50581:2012
CE Certificate:	CE 00999

I hereby declare that the equipment named above has been designed and manufactured in accordance with the relevant sections of the above referenced Directive(s) and Standard(s). The unit complies with all essential requirements of the Directives.


 Dan Sigak
 Director, Global Regulatory Affairs & Quality Compliance
 Varex Imaging Corporation
 1678 South Pioneer Road
 Salt Lake City, Utah 84104 USA

Dec. 1, 2016
 Date

Varex Imaging Corporation
X-Ray Tube Model List

A-102/B-100	A-102/DIAMOND	A-102/HRT-09	A-102/HRT-09N
A-102/MX7518NR	A-102/PX1300	A-102/HRT-0RN-18	A-132/B-100
A-132/DIAMOND	A-132/HRT-09N	A-132/MX7518NR	A-132/HRT-0RN-18
A-132/MX7509R	A-132/MX75FLR	A-134/B-100	A-134/DIAMOND
A-141/B-100	A-142/B-100	A-142/DIAMOND	A-144/B-100
A-145/B-145A	A-145/B-145W	A-145/DIAMOND	A-152/B-130H
A-152/B-135H	A-152/B-150H	A-182/B-130H	A-182/B-135H
A-182/B-150H	A-184/B-130H	A-184/B-135H	A-184/B-150H
A-185/B-150H	A-186/B-150H	A-187/B-150H	A-192/B-130H
A-192/B-135H	A-192/B-150	A-192/B-150H	A-192/DRX3724
A-192/PX1400	A-192B/B-130H	A-192B/B-150H	A-192B/DRX3724
A-192B/PX1400	A-194/B-130H	A-194/B-135H	A-194/B-150H
A-195/B-130H	A-195/B-135H	A-195/B-150H	A-195/DX62
A-195/MX100-09	A-195/MX100-18	A-195/MX100FLXR	A-196/B-130H
A-196/B-135H	A-196/B-150H	A-196/MX100-09	A-196/MX100-18
A-196/MX100FLXR	A-197/B-130H	A-197/B-135H	A-197/B-150H
A-252/B-130H	A-252/B-135H	A-252/B-150H	A-252/DX62
A-254/B-130H	A-254/B-135H	A-254/B-150H	A-256/B-130H
A-256/B-135H	A-256/B-150H	A-272/B-130H	A-272/B-135H
A-272/B-150H	A-274/B-130H	A-274/B-135H	A-274/B-150H
A-277/B-130H	A-277/B-135H	A-277/B-150H	A-278/B-130H
A-278/B-135H	A-278/B-150H	A-282/B-130H	A-282/B-135H
A-282/B-150H	A-284/B-130H	A-284/B-135H	A-284/B-150H
A-286/B-130H	A-286/B-135H	A-286/B-150H	A-287/B-130H
A-287/B-135H	A-287/B-150H	A-292/B-130H	A-292/B-135H
A-292/B-147	A-292/B-150H	A-292/PX1400	A-292/DX62
A-294/B-130H	A-294/B-135H	A-294/B-150H	A-297/B-130H
A-297/B-146H	A-297/B-148H	A-492/B-130HM	A-496/B-130HM
CG-292/S240	CG-292/S260	G-1077/B-160H	G-1077/B-165H
G-1078/B-160H	G-1078/B-165H	G-1078/MX100HTG	G-1080/B-160H
G-1080/B-165H	G-1081/B-160H	G-1081/B-165H	G-1082/B-160H
G-1082/B-165H	G-1084/B-160H	G-1084/B-165H	G-1086/B-160H
G-1086/B-165H	G-1087/B-160H	G-1092/B-160H	G-1092/B-165H
G-1092/MX120	G-1092/S550	G-1094/B-160H	G-1094/B-165H
G-1582BI/B-180H	G-1582BI/B-185H	G-1582BI-G/B-180H	G-1582BI-W/B-180H
G-1582BI-WR/B-180H	G-1582TRI/B-180H	G-1582TRI/B-185H	G-1584TRI/B-280H
G-1592/B-180H	G-1592/B-185H	G-1593BI/B-180H	G-1593BI/B-185H
G-1593TRI/B-180H	G-1593TRI/B-185H	G-1598TRI/B-283H	G-1599BI/B-244H
G-1599BI/B-284H	G-1599TRI-G/B-244H	G-1599TRI-G/B-284H	G-1599BI-G/B-244H
G-1599BI-G/B-284H	G-1599TRI/B-244H	G-1599TRI/B-284H	G-2064/B-282H
G-2090/B-240H	G-242/B-130H	G-242/B-147	G-256/B-130H
G-256/B-135H	G-256/B-147	G-256/B-150H	G-286/B-130H
G-286/B-135H	G-286/B-147	G-286/B-150H	G-287/B-130H
G-287/B-135H	G-287/B-147	G-287/B-150H	G-292/B-130H
G-292/B-135H	G-292/B-147	G-292/B-150H	G-292/MX100-09
G-292/MX100-18	G-292/S550	G-294/B-130H	G-294/B-147

Varex Imaging Corporation
X-Ray Tube Model List

G-295/B-130H	G-295/B-135H	G-295/B-147	G-296/B-130H
G-296/B-147	G-297/B-130H	G-297/B-146H	G-297/B-147
G-297/B-150H	G-298/B-130H	G-298/B-147	G-689/B-147
G-692/B-130HM	G-692/B-146HM	G-692/B-147	G-696/B-130HM
G-696/B-146HM	G-696/B-147	G-892/B-130H	G-892/B-146H
G-892/B-147	G-896/B-130H	G-896/B-146H	G-896/B-147
GS-1079/B-190H	GS-1089/B-160H	GS-1093/B-160H	GS-1275/B-194
GS-1542/B-182	GS-1562/B-172H	GS-1562/MX115CT	GS-1575/B-192H
GS-1579/B-180H	GS-1580/B-180H	GS-1584/B-230H	GS-1585/B-180H
GS-1587/B-180H	GS-1588B/B-180H	GS-1597/B-180H	GS-2030/B-300
GS-2030/B-300H	GS-2070/B-200	GS-2071/B-220H	GS-20711/B-220H
GS-20712/B-220H	GS-2072/B-200	GS-2075/B-220H	GS-2075A/B-240H
GS-2076/B-205H	GS-2077/B-220H	GS-2078/B-220H	GS-2078A/B-240H
GS-2079/B-210H	GS-2086IQ/B-242H	GS-2086PQ/B-242H	GS-2096/B-225H
GS-2176/MX135MV	GS-2276/B-206H	GS-2276/MX135CT-H1	GS-270/B-150H
GS-270/CT MAX	GS-297/B-130	GS-298/B-130	GS-3070/B-240H
GS-3071/B-240H	GS-30711/B-240	GS-3072/B-240H	GS-3073/B-240H
GS-3074/B-245H	GS-3075A/B-240H	GS-3077/B-240 HEL	GS-3078A/B-240H
GS-3576HS/MX165CT	GS-3576PS/MX165Z J	GS-3576S/DA165S	GS-3576S/B-306H
GS-3576S/MX165NP	GS-4070/B-500H	GS-4570/B-421H	GS-4571/B-421H
GS-4573/B-421H	GS-4575/B-420H	GS-4577/B-421H	GS-5075/B-501H
GS-5076/B-590H	GS-5079/B-502H	GS-5179/B320H	GS-532B/AKRON B
GS-532Q/AKRON Q	GS-6070/B-500H	GS-6071/B-550H	GS-6076/B-590H
GS-6078/B-501H	GS-6079/B-502H	IM-113R	IM-313TGB
M-101/B-110	M-101/B-112	M-101G/B-112	M-105SP/B-110
M-109/B-110	M-113/B-112	M-113/B-115	M-113/B-121
M-113-1A/B-115	M-113R/B-115	M-113R/B-121	M-113SP/B-110
M-113SP/B-112	M-113SP/B-115	M-113SP/B-121	M-113T/B-110
M-113T/B-115	M-113T/B-121	M-119T/B-110	M-119T/B-115
M-146/B-115	M-146SP/B-110	M-146SP/B-115	M-147/B-110
M-147/B-115	M-147SP/B-110	M-149/B-110	M-151/M51
M-152/M52.2	M-153/M52.2	M-171/B-110	M-185L/B-115
M-1580/B-128H	M-1581/B-128H	M-1582/B-128H	MC-1585/B-800
P-456/ROT360	P-456/ROT500	P-456/ROT501	P-456/ROT507
P-483/ROT500	P-483/ROT501	P-493/ROT500	P-493/ROT501
PG-256/ROT350	PG-256/ROT351	PG-256/ROT360	PG-292/ROT350
PG-292/ROT351	PG-292/ROT360	RAD-4/DIAMOND	RAD-4/EMERALD
RAD-8/EMERALD	RAD-8/DIAMOND	RAD-8/Leo	RAD-10/AMX4
RAD-10/DIAMOND	RAD-10/HRT-09N	RAD-11/MX75H.1	RAD-12/DIAMOND
RAD-12/Leo	RAD-13/DIAMOND	RAD-13/Leo	RAD-13/S240
RAD-13/S260	RAD-13/B-100	RAD-13/MX7518N	RAD-14/DIAMOND
RAD-14/HRT-09N	RAD-14/Leo	RAD-14/ORIII	RAD-14/ORIII B
RAD-14/PX1300	RAD-14/S240	RAD-21/DX62	RAD-21/MX100-18
RAD-21/RX80	RAD-21/RX85	RAD-21/SAPPHIRE	RAD-34/ROT350
RAD-34/ROT351	RAD-34/ROT360	RAD-44/B-130H	RAD-44/B-150H
RAD-44/PX1400	RAD-44/RX80	RAD-44/RX85	RAD-44/SAPPHIRE

Varex Imaging Corporation
X-Ray Tube Model List

RAD-50/ROT350	RAD-50/ROT351	RAD-50/ROT360	RAD-56/SAPPHIRE
RAD-56/PX1400	RAD-60/B-130H	RAD-60/B-135H	RAD-60/B-147
RAD-60/DX62	RAD-60/PX1400	RAD-60/RX85	RAD-60/SAPPHIRE
RAD-68/DIAMOND	RAD-68/EMERALD	RAD-68/Leo	RAD-68/S240
RAD-70/MAMRAD105H	RAD-70B/MAMRAD105H	RAD-70D/MAMRAD105H	RAD-73/MAMRAD100H
RAD-73B/MAMRAD100H	RAD-74/EMERALD	RAD-74/DIAMOND	RAD-74/Leo
RAD-85S/B-110	RAD-85S/B-112	RAD-92/B-130H	RAD-92/B-135H
RAD-92/B-147	RAD-92/B-150H	RAD-92/PX1400	RAD-92/DRX3724
RAD-92/SAPPHIRE	RAD-92/RX85	RAD-94/B-130H	RAD-94/B-135H
RAD-94/B-147	RAD-94/SAPPHIRE	RAD-99/B-145A	RAD-99/ORIII
RAD-99/ORIII B	RAD-99B/B-145W	RAD-99B/ORIII	RAD-99B/ORIIIB
S-270/B-150H	S-270/CT MAX	S-778/B-160H	S-780/B-160H
S-785/B-160H	SG-1096/B-199	SG-1096/OPTI150	SG-1096S/OPTI150
SG-1392/B-199	SG-1392/MEGALIX	SG-1392/MEGALIX-W	SG-1392/OPTI150
SG-1560/MEGALIX	SG-1560/MEGALIX-W	SG-1560S/MEGALIX	SG-1560S/MEGALIX-W
SG-1590/MEGALIX	SG-1590BI S/MEGALIX-W	SG-1590BI/MEGALIX-W	SG-1590TRI S/MEGALIX-W
SG-1590TRI/MEGALIX-W	SG-256B/B-199	SG-256B/OPTI150	SG-256S/OPTI150
SG-292B/B-199	SG-292B/OPTI150	SG-296B/B-199	SG-296B/OPTI150
SG-796/MEGALIX	SG-796B/B-199	SG-796B/OPTI150	SG-796S/OPTI150
MCS-2093/B-693H	MCS-6074/B-580H	MCS-7070/B-605H	MCS-7070HP/B-612H
MCS-7073/B-610H	MCS-7074/B-620H	MCS-7074A/B-625H	MCS-7078D REV2/B-605H
MCS-7078D/B-605H	MCS-7079/B-609H	MCS-7080/B-612H	MCS-7088A/B-608H
MCS-7171A/B-807H	MCS-7178/B-805H	MCS-7178A/B-805H	MCS-72810/B-803H
MCS-7288/B-800H	MCS-8064/B-680H		



By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

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

Holds Certificate No:

FM 21804

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

The design, development, manufacture, distribution, and full refurbishment of industrial and medical X-ray generating tube products, X-ray imagers and imaging components.

For and on behalf of BSI:


Carlos Pitanga, Chief Operating Officer Assurance – Americas

Original Registration Date: 1992-10-13

Latest Revision Date: 2018-08-21

Effective Date: 2018-08-21

Expiry Date: 2021-08-20



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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

This is to certify that:

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

Holds Certificate No:

FM 77566

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 for the following scope:

The design, development, manufacture, distribution and full refurbishment of medical X-ray generating tube products and X-ray imagers and imaging components.

For and on behalf of BSI:

Carlos Pitanga, SVP, System Certification and Compliance

Original Registration Date: 10/29/2003

Effective Date: 11/07/2016

Expiry Date: 02/28/2019



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Recognized
Registrar



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Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.

Certificate No: **FM 77566**

Location	Registered Activities
Varex Imaging Corporation 1678 South Pioneer Road Salt Lake City Utah 84104 USA	The design, development, manufacture, distribution and full refurbishment of medical X-ray generating tube products and X-ray imagers and imaging components.
Varex Imaging Corporation 3120 Hansen Way - Bldg 4 M/S G-103 Palo Alto California 94043 USA	The design and development of X-ray imaging components.



Original Registration Date: 10/29/2003 Effective Date: 11/07/2016 Expiry Date: 02/28/2019

Page: 2 of 2

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Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.