

bsi.



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):

Albert Roossien, Regulatory Lead

First Issued: **1995-11-15**

Date: **2019-03-25**

Expiry Date: **2020-01-27**

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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, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.



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: **2019-03-25**
 Issued To: **Varex Imaging Corporation**
1678 South Pioneer Road
Salt Lake City
Utah
84104
USA

Subcontractor:

Service(s) supplied

Arazy Group GmbH.
 Am Kalkhofen 8
 Wöllstadt,
 61206
 Germany

EU Representative

Varex Imaging Corporation
 3235 Fortune Drive
 North Charleston
 South Carolina
 29418
 USA

Manufacture

Varex Imaging Deutschland AG
 Otto-Brenner-Str. 10
 Willich
 D 47877
 Germany

Manufacture

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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: **2019-03-25**
Issued To: **Varex Imaging Corporation**
1678 South Pioneer Road
Salt Lake City
Utah
84104
USA

Subcontractor:

Varex Imaging Equipment (China) Co., Ltd.
Building G Plainvim international P
No. 30 Wanquan Road
Xishan District Wuxi
Jiangsu
214101
China

Service(s) supplied

Manufacture

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Page 2 of 2

EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 00999**
 Date: **2019-03-25**
 Issued To: **Varex Imaging Corporation**
1678 South Pioneer Road
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Utah
84104
USA

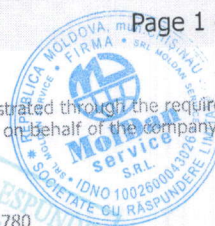
Date	Reference Number	Action
15 November 1995	-	First Issue.
17 September 1996	-	Addition of 'refurbishment' to the scope.
05 August 1998	-	Addition of sub-contractor 'VARIAN INTERAY' for 'The full refurbishment of X-ray tubes and the design and manufacture of amorphous-silicon flat panel imaging systems'.
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 3

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
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EC Certificate - Full Quality Assurance System

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Certificate No: **CE 00999**
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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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Page 2 of 3

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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.
Current	8939261	Traceable to NB 0086.

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Page 3 of 3

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By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Varex Imaging Corporation
3235 Fortune Drive
North Charleston
South Carolina
29418
USA

Holds Certificate No:

FM 84906

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The manufacture, distribution and repair of medical X ray generating tube products and distribution and repair of digital image receptors.

For and on behalf of BSI:


Chief Operating Officer Assurance - Americas

Original Registration Date: 2005-08-15
Latest Revision Date: 2018-06-01

Effective Date: 2018-06-06
Expiry Date: 2021-06-05

Page: 1 of 2



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This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](http://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

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 84906**

Location

Registered Activities

Varex Imaging Corporation
3235 Fortune Drive
North Charleston
South Carolina
29418
USA

The manufacture, distribution, and repair of medical X-ray generating tube products.

Varex Imaging
Deutschland AG
Karl-Arnold Strasse 12
Willich
47877
Germany

The manufacture, distribution and repair of medical X ray generating tube products and distribution and repair of digital image receptors



COPIA CORESPUNDE
ORIGINALULUI

Original Registration Date: 2005-08-15

Latest Revision Date: 2018-06-01

Effective Date: 2018-06-06

Expiry Date: 2021-06-05

Page: 2 of 2



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To be read in conjunction with the scope above or the attached appendix.

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

CE EC Declaration of Conformity



We:	EC Representative:
Varex Imaging Corporation 1678 S. Pioneer Road Salt Lake City, UT 84104 USA	Arazy Group GmbH. Am Kalkofen 8 Wöllstadt, 61206 Germany

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:	For MDD Only, BSI, Notified Body Number 2797
Classification:	Class IIb (Annex IX 3.2, Rule 10)
Applicable Standards:	EN 60601-1:2006/A1:2013 IEC 60601-1:2005/A1:2012 EN 60522:1999 EN 60601-1-3:2008 EN 60601-2-28:2010 IEC 60336:2005 IEC 60526:1978 IEC 60613:2010 EN ISO 13485:2016 EN 50581:2012
CE Certificate:	CE 00999

Varex Imaging Corporation hereby declares 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.

Martin Vidrine

Martin Vidrine,
Regulatory Affairs Manager
Varex Imaging Corporation
1678 South Pioneer Road
Salt Lake City, Utah 84104 US

14 May 2019



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-291/ORIV
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



Varex Imaging Corporation
X-Ray Tube Model List

G-294/B-147	G-294/ORIV	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-298/ORIV	G-689/B-146H	G-689/B-147
G-689/ORIV	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-5171/B-320H
GS-5172/B-320H	GS-5177/B-320H	GS-5179/B-320H	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-103T/B-121
M-103TGB/B-121GB	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-10/MX75	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/PX1400



Varex Imaging Corporation
X-Ray Tube Model List

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
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/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			



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