

Varex Imaging Deutschland AG Otto-Brenner-Strasse, 10 D-47877 Willich Tel: +49 2154 - 9249-80

Fax: +49 2154 - 9249-94 www.vareximaging.com

## TO WHOM IT MAY CONCERN

Willich, June 24th, 2019

## LETTER OF AUTHORIZATION

We, Varex Imaging Deutschland AG, located in Otto-Brenner Str. 10, 47877 Willich / Germany, manufacturer of X-Ray Tubes, herewith declare, that the Company:

"MolDan Service" SRL Sciusev Str. 16, suite 2, Chisinau, MD-2001 Republic of Moldova

is authorized to participate in the Public Tender no. 21009034, as well as to sell and to provide service for our products.

Yours sincerely Varex imaging

Deutschland AG

Otto - Brenner - Str.10

D-47877 Willich

Oppositions Manager: +49 21 54 - 9249-80

Fax: +49 21 54 - 9249-94

Aufsichtsrat: Kimberley E. Honeysett (Aufsichtsratsvorsitzende) Vorstand: Dr. Robert Hannemann, Marcus Kirchhoff, Dirk Schimmelschulze

Bankverbindung: Commerzbank Bremen IBAN: DE41 2904 0090 0100 4787 00 BIC: COBADEFFXXX Sitz: Willich



COPIA CORESPUNDE ORIGINALULUI



## Medical X-Ray Tube Warranty

Varex Imaging Corporation ("Varex") warrants its X-Ray Tubes ("X-Ray Tubes") as follows:

### X-Ray Tube Limited Warranty

Varex warrants the X-Ray Tubes it manufactures to be free from defects in material and workmanship that impair their performance and to be in substantial compliance with operational features of Varex's published specifications at the time of sale. Varex's warranty shall continue for the period of time specified below or as specified on Varex's quotation or agreed to in writing by Varex.

#### X-Ray Tube Warranty Periods

Standard warranty periods for particular X-Ray Tubes are listed below. If no period of time is so stated or agreed, then Varex's warranty is limited to thirty (30) days. Different standard or agreed warranty periods may apply.

Varex X-Ray Tube Type	Standard Warranty Periods	
Medical/Glass (1)	12 Months Non-Pro rata*	
Mammography	12 Months Pro rata*	
Metal Center Section Tubes	12 Months Pro rata**	

(1) Optional 24 Month Pro rata Warranty - see reverse side

\*Warranty period is twelve (12) months from date of installation but in no event later than eighteen (18) months from date of shipment from Varex's factory.

#### Remedies

If Varex examination confirms that an X-Ray Tube has failed during the Warranty Period through no fault of Customer, the Customer's sole and exclusive remedy shall be according to one of the following:

Non-Pro rata Period - If failure occurs during a non-pro rata Warranty Period, Varex will, at Varex's option and at no cost to Customer, either repair or replace the X-Ray Tube upon return of the failed X-Ray Tube to Varex. The warranty period remaining on the X-Ray Tube, at the time the tube is taken out of service, shall apply to the repaired tube or the replacement tube that is returned to the Customer by Varex.

Pro rata Period - If failure occurs during a pro rata warranty period, Varex will at Varex's sole option either: (1) refund the pro rata portion of the purchase price, (2) repair the X-Ray Tube, at no cost to the Customer, upon return of failed X-Ray Tube to Varex, or (3) apply a pro rata credit on a replacement order for a new X-Ray Tube. Refund or credit amount is determined as follows:

Credit = 
$$(A - B) \left\{ \frac{C - D}{C} \right\} + B$$

Where; A

A = Purchase Price

B = Trade-in credit/Exchange credit

C = Number of warranty days

 $\mathbf{D}$  = Number of days of use

**Note:** Industrial X-Ray Tubes and CT X-Ray Tubes are warranted as specified on separate Varex Warranty forms for the specific type of X-Ray Tube.

#### X-Ray Tube Warranty Conditions

All remedies are expressly conditioned on all the following:

- Repairs and adjustments of X-Ray Tubes must be made (or directed in writing) by authorized Varex personnel only. Unauthorized repairs or adjustments will void this warranty.
- 2. The X-Ray Tube must have been used under normal operating conditions within the respective Varex-specified ratings and according to Varex operating

instructions. Misuse, abuse, or improper installation will void this warranty. Varex shall make the sole final determination about whether failure occurred in normal operation (under warranty) or whether the X-Ray Tube was subjected to other than normal operation (excluded from warranty).

- 3. Customer must give Varex written notice of X-Ray Tube failure before the end of the X-Ray Tube Warranty Period, and return it prepaid to Varex with a completed TUBE SERVICE REPORT describing the reason for return, operating conditions, dates of installation and removal, counter readings at installation and removal, and other pertinent information. Varex may solely determine probable number of scans or hours of usage of the X-Ray Tube when no accurate records can be found. All repairs not within warranty will be invoiced at prevailing rates, but Varex will not begin work without Customer's approval of charges.
- 4. Unless otherwise agreed by Varex, Customer shall pay costs of shipping for X-Ray Tubes returned to Varex for repair or adjustment, shall be responsible for loss or damage in transit, and shall file claims for loss or damage in transit.
- 5. The Warranty Period remaining on the date Varex received notice of failure shall apply to the repaired or replaced X-Ray Tube from the date of reshipment to Customer.

#### **Exclusions from Coverage**

Varex's warranties shall not apply to the extent that malfunction is caused in Varex's reasonable opinion by (1) accident, abuse, alteration, misuse, or neglect, (2) failure to use Products under normal operating conditions or environment, or within Varex specified ratings, or according to any operating instructions provided by Varex, (3) lack of routine care or maintenance as indicated in any Varex operating or maintenance instructions, (4) failure to use or take any proper precautions under the circumstances, (5) user modification of any Product or Software, or (6) latent defects discovered after expiration of the applicable warranty period. This warranty does not cover Buyer-supplied software, equipment warranted by another manufacturer, or replacement of expendable, consumable, or limited life items.

### **Exclusion of Implied Warranties**

This limited warranty is expressly in lieu of and EXCLUDES all other express or implied warranties including but not limited to warranties of MERCHANTABILITY and of FITNESS for a particular purpose, use, or application.

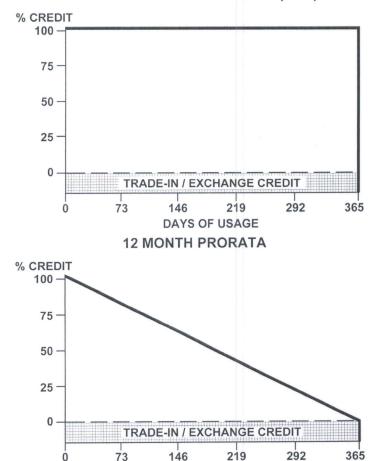
Limitations on Damages and Liability

VAREX'S TOTAL LIABILITY IN DAMAGES OR OTHERWISE SHALL NOT EXCEED THE PAYMENT, IF ANY, RECEIVED BY Varex FOR THE UNIT OF PRODUCT, SERVICE OR SOFTWARE FURNISHED OR TO BE FURNISHED RESULTING IN THE LOSS OR DAMAGE CLAIMED. IN NO EVENT SHALL VAREX BE LIABLE FOR INCIDENTAL, CONSEQUENTIAL, INDIRECT, PUNITIVE, OR SPECIAL LOSS OR DAMAGES OF ANY KIND, SUCH AS, BUT NOT LIMITED TO, LOST BUSINESS REVENUE, LOST PROFITS, OR COSTS OF DOWNTIME RESULTING FROM VAREX'S PRODUCTS, SERVICES, OR SOFTWARE, HOWEVER CAUSED, WHETHER BASED ON CONTRACT, TORT (INCLUDING NEGLIGENCE), OR ANY OTHER LEGAL THEORY. Liability to third parties for bodily injury, including death, resulting from Varex's performance or Products shall be determined according to applicable law. No claims, regardless of form, arising out of, or in any way connected with Products, Software, or Services furnished by Varex, may be brought by Buyer more than one (1) year after the cause of action has decribed or Varex's performance has been completed or terminated, whichever



## STANDARD WARRANTY

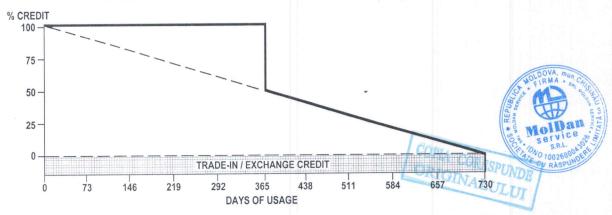
12 MONTH NON-PRORATA (NPR)



## MEDICAL/GLASS TUBE - OPTIONAL WARRANTY

DAYS OF USAGE

24 MONTH PRORATA WITH 12 MONTH NON-PRORATA (NPR)







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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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the 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.





By Royal Charter

## 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	11 <u>1</u>	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	

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.

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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
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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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.





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:

For MDD Only, BSI, Notified Body Number 0086

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 13485:2012

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.

Martin Vidrine,

Regulatory Affairs Specialist III Varex Imaging Corporation

1678 South Pioneer Road

Salt Lake City, Utah 84104 US

25 JAN 2018



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## 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	FP-1000	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-1080/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

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## Varex Imaging Corporation X-Ray Tube Model List

G-294/B-147	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-146H	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-5171/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-8/Leo	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/ORIII	RAD-14/ORIII B	RAD-14/PX1300
RAD-14/Leo	RAD-14/ORIII RAD-21/DX62	RAD-21/MX100-18	RAD-21/PX1400
RAD-14/S240 RAD-21/RX80	RAD-21/DX02	RAD-21/SAPPHIRE	RAD-34/ROT350

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## Varex Imaging Corporation X-Ray Tube Model List

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/RX85	RAD-60/SAPPHIRE	RAD-68/DIAMOND
RAD-60/DX62	RAD-68/Leo	RAD-68/S240	RAD-70/MAMRAD105H
RAD-68/EMERALD RAD-	RAD-	RAD-73/MAMRAD100H	RAD-
70B/MAMRAD105H	70D/MAMRAD105H		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-94/B-130H	RAD-94/B-135H	RAD-94/B-147
RAD-92/RX85 RAD-94/SAPPHIRE	RAD-99/B-145A	RAD-99/ORIII	RAD-99/ORIII B
	RAD-99B/ORIII	RAD-99B/ORIIIB	S-270/B-150H
RAD-99B/B-145W	S-778/B-160H	S-780/B-160H	S-785/B-160H
S-270/CT MAX	SG-1096/OPTI150	SG-1096S/OPTI150	SG-1392/B-199
SG-1096/B-199	SG-1392/MEGALIX-W	SG-1392/OPTI150	SG-1560/MEGALIX
SG-1392/MEGALIX	SG-1560S/MEGALIX	SG-1560S/MEGALIX-W	SG-1590/MEGALIX
SG-1560/MEGALIX-W	SG-1590BI/MEGALIX-	SG-1590TRI	SG-1590TRI/MEGALIX
SG-1590BI	The state of the s	S/MEGALIX-W	W
S/MEGALIX-W	W   SG-256B/OPTI150	SG-256S/OPTI150	SG-292B/B-199
SG-256B/B-199	SG-296B/B-199	SG-296B/OPTI150	SG-796/MEGALIX
SG-292B/OPTI150	SG-796B/OPTI150	SG-796S/OPTI150	MCS-1000
SG-796B/B-199		MCS-7070/B-605H	MCS-7070HP/B-612H
MCS-2093/B-693H MCS-7073/B-610H	MCS-6074/B-580H MCS-7074/B-620H	MCS-7074A/B-625H	MCS-7078D REV2/B- 605H
	1000 7070/D (00II	MCS-7080/B-612H	MCS-7088A/B-608H
MCS-7078D/B-605H	MCS-7079/B-609H	MCS-7178A/B-805H	MCS-72810/B-803H
MCS-7171A/B-807H	MCS-7178/B-805H	WCS-717674D-60311	
MCS-7288/B-800H	MCS-8064/B-680H		



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## Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

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 13485:2016 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:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2003-10-29 Latest Revision Date: 2018-11-28 Effective Date: 2018-11-28 Expiry Date: 2021-06-05

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## 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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