

#### NATIONAL ACCREDITATION CENTER

### **ACCREDITATION CERTIFICATE**

TO BE ACTIVE AS INSPECTION BODY,

ATA KALİBRASYON SAN. ve TİC. LTD. ŞTİ.

ŞERİFALİ MAH. EDEP SOK. NO:45 Y.DUDULLU ÜMRANİYE İSTANBUL/TÜRKİYE.

As a result of the audit conducted by the National Accreditation Center (NAC), it is accredited in the annexes to the ISO / IEC 17020: 2012 Conformity assessment; Requirements for the operation of various types of bodies performing inspection

> Accreditation Number: NAC-001-IB Accreditation Date: 05.04.2019

This certificate is valid until 05 April 2020, if the above mentioned name and address continue to comply with the relevant standards, international and regional rules in addition to the written organization's ISO / IEC 17020: 2012 Conformity Assessment; Requirements for the Operation of Various Types of Bodies Performing Inspection.



This certificate is given by NAC. The certificate becomes invalid in case of suspension and cancellation of accreditation. For current accreditation information, visit www.nationalaccreditationcenter.org or communicate with NAC on info@nationalaccreditationcenter.org.



#### Attachment of Accreditation Certificate (Page 1/13)

#### Scope of Accreditation



Scope of Accidation				
NAC ACCREDITATION NUMBER	NAC-001-IB			
COMPANY NAME	ATA KALİBRASYON SAN. ve TİC. LTD.ŞTİ			
ADRESS:	Şerifali Mah. Edep Sok. No45 Y.Dudullu Ümraniye / İSTANBUL			
CONTACT NAME :	ERKAL KETENCİ			
TELEPHONE :	0 216 398 48 08			
ACCREDITATION DATE :	05.04.2019			
ACCREDITATION STANDARD :	ISO/IEC 17020:2012			

ACCREDITATION AREA:  ACCREDITATION STANDARD:		Conformity assessment Requirements for the operation  of various types of bodies performing inspection  ISO/IEC 17020:2012		
Certification Sectors				
Inspection Area	Inspectio	п Туре	Standard /Specification	
MEDICINE AND MEDICAL DEVICE	HVAC SYSTEM OPERA	TION /	-T.C.S.B - GMP	
MATERIAL PRODUCTION AREAS PERFORMANCE QU		FICATION (OQ /	-EUDRALEX Volume 4: Annex	
	PQ)		1: 2008-GMP Medicinal	
DPERATING ROOMS			Products for Human and	
			Veterinary Use	
INTENSIVE CARE UNITS			-FDA cGMP: 2004-Sterile Drug	
			Products Produced by Aseptic	
FOOD PRODUCTION AREAS			Processing	
			-T.C.S.B - SPECIAL HOSPITALS	
MICRO ELECTRONIC PARTS			REGULATION	
PRODUCTION AREAS			-SKS Quality Standards in Health	
	AIR FLOW, AIR SPEEL	) and	IEST-RP-CC006.3	

SAMENESS MEASUREMENT



OTHER AREAS USING CLEAN

OR/ AND HYGIENIC ROOMS

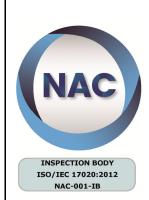
#### **National Accreditation Center**

ISO 14644-2 ISO 14644-3

DIN 1946-4

#### Attachment of Accreditation Certificate (Page 2/13)

#### Scope of Accreditation

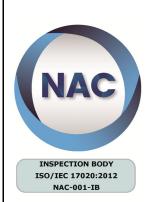


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ACCREDITATION DATE :	05.04.2019			
ACCREDITATION STANDARD :	ISO/IEC 17020:2012			

ACCREDITATION AREA:		Conformity assessment Requirements for the operation of various types of bodies performing inspection			
ACCREDITATION STANDARD:		ISO/IEC 17020:2012			
Certification Sectors					
Inspection Area	Inspection	Туре	Standard /Specification		
MEDICINE AND MEDICAL DEVICE / MATERIAL PRODUCTION AREAS	HEPA and ULPA FILTER LEAKAGE TEST	? EQUIPMENT	IEST-RP-CC034.3 IEST-RP-CC006.3 ISO 14644-2 ISO 14644-3 DIN 1946-4		
OPERATING ROOMS INTENSIVE CARE UNITS	NUMBER OF PARTICLES	OF CLEAN ROOM	IEST-RP-CC006.3 ISO 14644-1 ISO 14644-2 DIN 1946-4		
FOOD PRODUCTION AREAS	MEASURING OF THE PRESSURE DIFFERENC	E	IEST-RP-CC006.3 ISO 14644-2 ISO 14644-3 DIN 1946-4		
MICRO ELECTRONIC PARTS PRODUCTION AREAS	TEMPERATURE AND HU MEASUREMENT		IEST-RP-CC006.3 ISO 14644-3 DIN 1946-4		
OTHER AREAS USING CLEAN OR/ AND HYGIENIC ROOMS					



## Attachment of Accreditation Certificate (Page 3/13) Scope of Accreditation



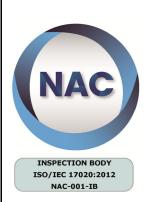
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ACCREDITATION AREA:  ACCREDITATION STANDARD:		Conformity assessment Requirements for the operation of various types of bodies performing inspection  ISO/IEC 17020:2012	
	Certificatio	n Sectors	
Inspection Area	Inspectio	on Type	Standard /Specification
MEDICINE AND MEDICAL DEVICE / MATERIAL PRODUCTION AREAS	VISUALIZATION TES		IEST-RP-CC006.3 ISO 14644-2 ISO 14644-3 DIN 1946-4
OPERATING ROOMS			

OPERATING ROOMS		
INTENSIVE CARE UNITS FOOD PRODUCTION AREAS	,	IEST-RP-CC006.3 ISO 14644-2 ISO 14644-3 DIN 1946-4
MICRO ELECTRONIC PARTS PRODUCTION AREAS OTHER AREAS USING CLEAN OR/ AND HYGIENIC ROOMS	LEAKING MEASUREMENT OF CLEAN ROOM	ISO 14644-3 DIN 1946-4



# Attachment of Accreditation Certificate (Page 4/13) Scope of Accreditation



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$\Gamma \Delta DRESS'$		Şerifali Mah. Edep Sok. No45 Y.Dudullu Ümraniye / İSTANBUL
	CONTACT NAME :	ERKAL KETENCİ
	TELEPHONE :	0 216 398 48 08
	ACCREDITATION DATE :	05.04.2019
	ACCREDITATION STANDARD :	ISO/IEC 17020:2012

ACCREDITATION A	REA:		essment Requirements for the operation of ypes of bodies performing inspection
ACCREDITATION STANDARD:		ISO/IEC 17020:2012	
	Certificatio	on Sectors	
Inspection Area	Inspection	п Туре	Standard /Specification
MEDICINE AND MEDICAL DEVICE / MATERIAL PRODUCTION AREAS	HVAC SYSTEM INSTALLATION QUAL	LIFICATION (IQ)	-TS EN 1507 -TS EN 12237

# MEDICINE AND MEDICAL DEVICE / MATERIAL PRODUCTION AREAS OPERATING ROOMS IN VENTILATION CHANNELS - Rectangular Air Ducts - Circular Section Air Ducts MICRO ELECTRONIC PARTS PRODUCTION AREAS OTHER AREAS USING CLEAN OR/ AND HYGIENIC ROOMS HVAC SYSTEM INSTALLATION QUALIFICATION (IQ) -TS EN 1507 -TS EN 12237 -ANSI/SMACNA-016 -BESA/DW 143 TEST OF STRENGTH AND LEAKING IN VENTILATION CHANNELS - Rectangular Air Ducts - Circular Section Air Ducts OTHER AREAS USING CLEAN OR/ AND HYGIENIC ROOMS COMFORT AREAS FUME CUPBOARD



## Attachment of Accreditation Certificate (Page 5/13) Scope of Accreditation

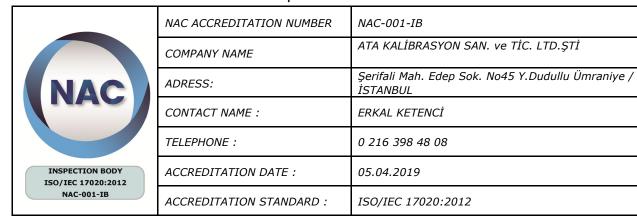


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	CONTACT NAME :	ERKAL KETENCİ
	TELEPHONE :	0 216 398 48 08
ACCREDITATION DATE :		05.04.2019
	ACCREDITATION STANDARD :	ISO/IEC 17020:2012

ACCREDITATION AREA:		Conformity assessment Requirements for the operation of various types of bodies performing inspection	
ACCREDITATION STANDARD:		ISO/IEC 17020:2012	
Certification Sectors			
Inspection Area	Inspection	n Type	Standard /Specification
BIO-SAFETY CABINS	-FILTER LEAKING TEST -MEASUREMENT OF AIR FLOW SPEED -VISUALIZATION OF AIR		EN 12469 WHO GLP ANSI /NSF 49
FUME CUPBOARD	PERFORMANCE QUALIA - TEST OF SURFACE SA - TEST OF ROOM AIR SA - TEST OF AIR FLOW - TEST OF ALARM REG	PEED SPEED VISUALIZATION	EN 14175-1 EN 14175-2 EN 14175-3 EN 14175-4 EN 14175-6



# Attachment of Accreditation Certificate (Page 6/13) Scope of Accreditation



ACCREDITATION AF	REA:		essment Requirements for the operation types of bodies performing inspection
ACCREDITATION STANDARD:			ISO/IEC 17020:2012
	Certificatio	n Sectors	
CLEAN ROOM	- SAMPLING - SURFACE BIO MEASUREMEN - AIR BIOCONT, MEASUREMEN - MICROBIOLOG QUALIFICATIO ASSESSMENT	CONTAMINATION TS AMINATION TS GICAL	ISO 14698-1 ISO 14698-2 ISO 14698-1 ISO 14698-2
Work Hygiene -Lighting	-Lighting in the Workp -Measurement of Light Level		COHSR-928-1-IPG-039
Work Hygiene- TS EN ISO 9612 Noise	- Measuring Noi Work Environr	ise Exposed in the ment	TS EN ISO 9612



## Attachment of Accreditation Certificate (Page 7/13) Scope of Accreditation



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ACCREDITATION DATE :	05.04.2019
ACCREDITATION STANDARD :	ISO/IEC 17020:2012

Conformity assessment Requirements for the operation of

ACCREDITATION AREA:		various types of bodies performing inspection		
ACCREDITATION STA	INDARD:	ISO/IEC 17020:2012		
	Certification	n Sectors		
Inspection Area	Inspection	1 Туре	Standard /Specification	
Ultrasound (Gray Scale)	Physical and mechanic Monitor setting and ac Image homogeneity Penetration (imaging) Distance accuracy Anechoic object imagin Axial separation capab Lateral separation cap Dead zone	depth ng illity	IPEM Report 102 AAPM Report 65	
Doppler Ultrasound, Echocardiography	Physical and mechanic Monitor setting and acc Image homogeneity Penetration (imaging) Distance accuracy Anechoic object imagin Axial separation capab Lateral separation capab Dead zone Doppler signal sensitiv Color Doppler flow sen Deep flow sensitivity Color Doppler - B-Mod Flow direction accuracy Flow rate reading accu Sample passage position	curacy  depth  ng ility ability ity sitivity image match racy	IPEM Report 102 AAPM Report 65	



# Attachment of Accreditation Certificate (Page 8/13) Scope of Accreditation



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CONTACT NAME :	ERKAL KETENCİ
TELEPHONE :	0 216 398 48 08
ACCREDITATION DATE :	05.04.2019
ACCREDITATION STANDARD :	ISO/IEC 17020:2012

ACCREDITATION AREA:	Conformity assessment Requirements for the operation of various types of bodies performing inspection
ACCREDITATION STANDARD:	ISO/IEC 17020:2012

#### **Certification Sectors**

Inspection Area	Inspection Type	Standard /Specification
Digital Radiography (DR)	Tube voltage (kVp)	IPEM Report 32
	Tube output and stability	IPEM Report 91
	Exposure repeatability and linearity	AAPM Report 74
	Exposure duration	AAPM Report 116
	Half-value layer and tube filtration	TS EN 61223-3-1
	Focus point size	TS EN 60336
	X-ray - Light field harmony and beam alignment	TS EN 60601-1-3
	Grid alignment	TS EN 60601-2-54
	Tube chassis leak radiation	TS EN 62220-1
	Automatic exposure control	European Commission Radiation Protection
	Detector dose index (DDI)	No 162
	Signal transmission feature	
	Noise	
	Visual evaluation and measurement of homogeneity	
	Broken detector element evaluation	
	Blur, line defects and mash artifact assessment	
	Mesh image artifact evaluation	
	Measurement of the rest in the image	
	Threshold contrast-detail perceptibility	
	Noise exchange with detector air kerma	
	Signal-to-noise ratio	
	High contrast separation capability	
	Scaling errors	
	Modulation transfer function (MTF)	
	Noise power spectrum (NPS)	
	Detection quantum efficiency (DQE)	



# Attachment of Accreditation Certificate (Page 9/13) Scope of Accreditation



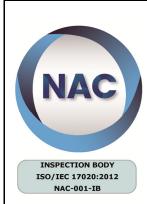
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ACCREDITATION DATE :	05.04.2019		
ACCREDITATION STANDARD :	ISO/IEC 17020:2012		

Conformity assessment Requirements for the operation of

ACCREDITATION AREA:		various types of bodies performing inspection			
ACCREDITATION STANDARD:			ISO/IEC 17020:2012		
		Certification	•		
Inspection Area		Inspection	Туре		Standard /Specification
	Tube voltage (kVp)			IPEM Re	•
	Tube output	and stability		IPEM Re	eport 91
Exposure repeatability and linearity			AAPM R	eport 74	
	Exposure duration			eport 116	
	Half value layer and tube filtration			TS EN 6	1223-3-1
	Focus point size			TS EN 60	
	X-ray - Light field harmony and beam alignment		gnment	TS EN 60	0601-1-3
	Grid alignment		TS EN 60601-2-54		
	Tube chassis leak radiation			TS EN 62220-1	
	Automatic exposure control			Europea	n Commission Radiation Protection No 162
Computed Radiography (CR) (Constant, Mobile)	Detector dose index (DDI)				
	Signal transmission feature				
(Constant, Mobile)	DDI repeatability				
	CR image plates co				
	Difference assessment between CR readers		ers		
	Noise				
	Homogeneity measurement				
Erase efficiency Threshold contrast-detail perceptibility					
	Noise exchange with detector air kerma Signal-to-noise ratio High contrast separation capability				
	Blur				
	Laser function evaluation				
	Scaling errors				
	Modulation transfer function (MTF)				
	Noise power spectrum (NPS)				
	Detection qua	antum efficiency (DQE)			



## Attachment of Accreditation Certificate (Page 10/13) Scope of Accreditation

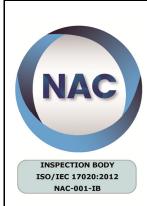


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ACCREDITATION DATE :	05.04.2019
ACCREDITATION STANDARD :	ISO/IEC 17020:2012

ACCREDITATION AREA:  ACCREDITATION STANDARD:		Conformity assessment Requirements for the operation of  various types of bodies performing inspection  ISO/IEC 17020:2012		
	Certificati	ion Sectors		
Inspection Area	Inspecti	on Type	Standard /Specification	
Film-Display Radiography Tube voltage (kVp)		1	IPEM Report 32	
(Constant, Mobile)	Tube output and stability		IPEM Report 91	
Exposure repeatab linearity Exposure duration		oility and	AAPM Report 74	
			TS EN 61223-3-1	
	Half value layer an filtration	d tube	TS EN 60336	
	Focus point size		TS EN 60601-1-3	
X-ray - Light field harmony beam alignment Grid alignment		armony and	TS EN 60601-2-54	
			European Commission Radiation Protection No 162	
	Tube chassis leak ra			
	Automatic exposu	re control		



# Attachment of Accreditation Certificate (Page 11/13) Scope of Accreditation

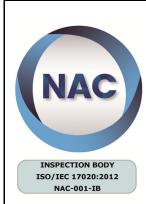


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ACCREDITATION AREA:  ACCREDITATION STANDARD:		Conformity assessment Requirements for the operation of  various types of bodies performing inspection  ISO/IEC 17020:2012		
Inspection Area	Inspecti	ion Type	Standard /Specification	
Mammography (Conventional)	Mammography sys	stem evaluation	IPEM Report 89	
	X-ray - Light field h	narmony	IPEM Report 91	
	X-ray - Film field h	armony	ACR Mammography QC Manual	
	Leaking radiation		NHSBSP No 63	
	Clamping force		IAEA HHS-2	
	Thickness indicato	r accuracy	TS EN 61223-3-2	
	Focus point size		TS EN 60336	
	Tube voltage (kVp	)	TS EN 60601-2-45	
	Half-value layer and tube filtration		<b>European Guidelines for Quality</b>	
	Tube output		Assurance in Breast Cancer Screening	
	Tube output repea	atability	and Diagnosis	
	Specific tube outp	ut	<b>European Commission Radiation</b>	
	Specific tube outp	ut speed	Protection No 162	
	Exchange of tune of	output with tube voltage		
	Exchange of tube output with mAs			
	Grid factor			
	Grid artifact			
	Image homogenei	ty		
	Automatic exposu	re control (AEC)		
	Target optical den	sity		
	Repeatability			
	Exchange with breast thickness			
	Exchange with tube voltage			
	Exposure duration			
	Protective timer			
	Average glandular	tissue dose		
	Clinical image qua	lity		
	High contrast sepa	ration capability		



## Attachment of Accreditation Certificate (Page 12/13) Scope of Accreditation



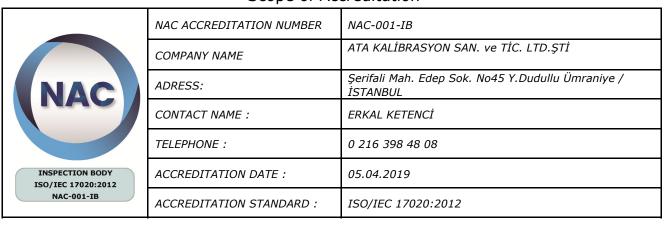
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				Certification Sectors		
Inspection Area	Inspection Type		Standard /Specification			
Mammography (Digital)	Mammography system evaluation		IPEM Report 89			
	X-ray - Light field harmony		IPEM Report 91			
	Leaking radiation		ACR Mammography QC Manual			
	Clamping force		NHSBSP No 63			
	Thickness indicator accuracy		NHSBSP Equipment Report 0604			
	Focus point size		NHSBSP Equipment Report 0902			
	Tube voltage (kVp)		IAEA HHS-17			
	Half-value layer and tube filtration		TS EN 61223-3-2			
	Tube output		TS EN 60336			
	Tube output repeatability		TS EN 60601-2-45			
	Specific tube output		TS EN 62220-1-2			
	Specific tube output speed		<b>European Guidelines for Quality</b>			
	Exchange of tune output with tube voltage		Assurance in Breast Cancer Screening			
	Exchange of tube output with mAs		and Diagnosis			
	Grid factor		<b>European Commission Radiation</b>			
	Grid artifact		Protection No 162			
	Image homogeneity					
	Automatic exposure control (AEC)					
	Target optical density					
	Repeatability					
	Exchange with breast thickness					
	Exchange with tub	e voltage				
	Exposure duration					
	Protective timer					
	Average glandular tissue dose					
	Clinical image quality					
	High contrast sepa	ration capability				

Modulation transfer function (MTF) Noise power spectrum (NPS) Detection quantum efficiency (DQE)



# Attachment of Accreditation Certificate (Page 13/13) Scope of Accreditation



ACCREDITATION AREA:		Conformity assessment Requirements for the operation of	
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ACCREDITATION STANDARD:		ISO/IEC 17020:2012	
	Certificat	ion Sectors	
Inspection Area	Inspection Type		Standard /Specification
Intra-Oral Dental Radiography	Tube voltage (kVp)		IPEM Report 91
(Conventional, Digital)	Exposure duration		<b>European Commission Radiation</b>
	Tube output		Protection No 162
	Half-value layer and tube filtration		NRPB Guidance Notes for Dental
	X-ray beam size		Practitioners on the Safe Use of X-Ray
	Image homogeneity		Equipment
	Limiting spatial separation capability		BIR - Assurance of Quality in the
	Dose measurement at the collimator output		Diagnostic Imaging Department
			TS EN 61223-3-4
			TS EN 60336

