



**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](http://www.nationalaccreditationcenter.org) or communicate with NAC on [info@nationalaccreditationcenter.org](mailto:info@nationalaccreditationcenter.org).

*Gaynor*  
GENERAL SECRETARY

## Scope of Accreditation

 <p>INSPECTION BODY ISO/IEC 17020:2012 NAC-001-IB</p>	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

<b>ACCREDITATION AREA:</b>		<b>Conformity assessment Requirements for the operation of various types of bodies performing inspection</b>
<b>ACCREDITATION STANDARD:</b>		<b>ISO/IEC 17020:2012</b>
<b>Certification Sectors</b>		
<b>Inspection Area</b>	<b>Inspection Type</b>	<b>Standard /Specification</b>
MEDICINE AND MEDICAL DEVICE / MATERIAL PRODUCTION AREAS  OPERATING ROOMS  INTENSIVE CARE UNITS  FOOD PRODUCTION AREAS  MICRO ELECTRONIC PARTS PRODUCTION AREAS  OTHER AREAS USING CLEAN OR/ AND HYGIENIC ROOMS	HVAC SYSTEM OPERATION / PERFORMANCE QUALIFICATION (OQ / PQ)	-T.C.S.B - GMP -EUDRALEX Volume 4: Annex 1: 2008-GMP Medicinal Products for Human and Veterinary Use -FDA cGMP: 2004-Sterile Drug Products Produced by Aseptic Processing -T.C.S.B - SPECIAL HOSPITALS REGULATION -SKS Quality Standards in Health
	AIR FLOW, AIR SPEED and SAMENESS MEASUREMENT	TEST-RP-CC006.3 ISO 14644-2 ISO 14644-3 DIN 1946-4




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<b>Certification Sectors</b>		
<b>Inspection Area</b>	<b>Inspection Type</b>	<b>Standard /Specification</b>
MEDICINE AND MEDICAL DEVICE / MATERIAL PRODUCTION AREAS	HEPA and ULPA FILTER EQUIPMENT LEAKAGE TEST	TEST-RP-CC034.3 TEST-RP-CC006.3 ISO 14644-2 ISO 14644-3 DIN 1946-4
OPERATING ROOMS INTENSIVE CARE UNITS	NUMBER OF PARTICLES and CLASSIFICATION OF CLEAN ROOM	TEST-RP-CC006.3 ISO 14644-1 ISO 14644-2 DIN 1946-4
FOOD PRODUCTION AREAS	MEASURING OF THE PRESSURE DIFFERENCE	TEST-RP-CC006.3 ISO 14644-2 ISO 14644-3 DIN 1946-4
MICRO ELECTRONIC PARTS PRODUCTION AREAS	TEMPERATURE AND HUMIDITY MEASUREMENT	TEST-RP-CC006.3 ISO 14644-3 DIN 1946-4
OTHER AREAS USING CLEAN OR/ AND HYGIENIC ROOMS		



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<b>Certification Sectors</b>		
<b>Inspection Area</b>	<b>Inspection Type</b>	<b>Standard /Specification</b>
<p>MEDICINE AND MEDICAL DEVICE / MATERIAL PRODUCTION AREAS</p> <p>OPERATING ROOMS</p> <p>INTENSIVE CARE UNITS</p> <p>FOOD PRODUCTION AREAS</p> <p>MICRO ELECTRONIC PARTS PRODUCTION AREAS</p> <p>OTHER AREAS USING CLEAN OR/ AND HYGIENIC ROOMS</p>	VISUALIZATION TEST OF THE AIR FLOW CHARACTERISTIC	TEST-RP-CC006.3 ISO 14644-2 ISO 14644-3 DIN 1946-4
	DECONTAMINATION / DETERMINATION OF RECOVERY TIME	TEST-RP-CC006.3 ISO 14644-2 ISO 14644-3 DIN 1946-4
	LEAKING MEASUREMENT OF CLEAN ROOM	ISO 14644-3 DIN 1946-4




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<b>Certification Sectors</b>		
<b>Inspection Area</b>	<b>Inspection Type</b>	<b>Standard /Specification</b>
MEDICINE AND MEDICAL DEVICE / MATERIAL PRODUCTION AREAS  OPERATING ROOMS  INTENSIVE CARE UNITS  FOOD PRODUCTION AREAS  MICRO ELECTRONIC PARTS PRODUCTION AREAS  OTHER AREAS USING CLEAN OR/ AND HYGIENIC ROOMS  COMFORT AREAS FUME CUPBOARD	HVAC SYSTEM INSTALLATION QUALIFICATION (IQ)  TEST OF STRENGTH AND LEAKING IN VENTILATION CHANNELS - Rectangular Air Ducts - Circular Section Air Ducts	TS EN 1507 TS EN 12237 ANSI/SMACNA-016 BESA/DW 143




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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
BIO-SAFETY CABINS	-PERFORMANCE QUALIFICATION (PQ) -FILTER LEAKING TEST -MEASUREMENT OF AIR FLOW SPEED -VISUALIZATION OF AIR FLOW DIRECTION -ALARM AND OTHER FUNCTIONS CONTROL	EN 12469 WHO GLP ANSI /NSF 49
FUME CUPBOARD	PERFORMANCE QUALIFICATION (PQ) - TEST OF SURFACE SPEED - TEST OF ROOM AIR SPEED - TEST OF AIR FLOW VISUALIZATION - TEST OF ALARM REGULATION	EN 14175-1 EN 14175-2 EN 14175-3 EN 14175-4 EN 14175-6




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<b>ACCREDITATION STANDARD:</b>		<b>ISO/IEC 17020:2012</b>
<b>Certification Sectors</b>		
CLEAN ROOM	<ul style="list-style-type: none"> <li>- SAMPLING</li> <li>- SURFACE BIOCONTAMINATION MEASUREMENTS</li> <li>- AIR BIOCONTAMINATION MEASUREMENTS</li> <li>- MICROBIOLOGICAL QUALIFICATION ASSESSMENT</li> </ul>	<p>ISO 14698-1</p> <p>ISO 14698-2</p> <p>ISO 14698-1</p> <p>ISO 14698-2</p>
Work Hygiene -Lighting	<ul style="list-style-type: none"> <li>-Lighting in the Workplace</li> <li>-Measurement of Light Intensity Level</li> </ul>	COHSR-928-1-IPG-039
Work Hygiene- TS EN ISO 9612 Noise	<ul style="list-style-type: none"> <li>- Measuring Noise Exposed in the Work Environment</li> </ul>	TS EN ISO 9612




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<b>Certification Sectors</b>		
<b>Inspection Area</b>	<b>Inspection Type</b>	<b>Standard /Specification</b>
Ultrasound (Gray Scale)	Physical and mechanical inspection Monitor setting and accuracy Image homogeneity Penetration (imaging) depth Distance accuracy Anechoic object imaging Axial separation capability Lateral separation capability Dead zone	IPEM Report 102 AAPM Report 65
Doppler Ultrasound, Echocardiography	Physical and mechanical inspection Monitor setting and accuracy Image homogeneity Penetration (imaging) depth Distance accuracy Anechoic object imaging Axial separation capability Lateral separation capability Dead zone Doppler signal sensitivity Color Doppler flow sensitivity Deep flow sensitivity Color Doppler - B-Mod image match Flow direction accuracy Flow rate reading accuracy Sample passage position accuracy	IPEM Report 102 AAPM Report 65



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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) Tube output and stability Exposure repeatability and linearity Exposure duration Half-value layer and tube filtration Focus point size X-ray - Light field harmony and beam alignment Grid alignment Tube chassis leak radiation Automatic exposure control Detector dose index (DDI) 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)	IPEM Report 32 IPEM Report 91 AAPM Report 74 AAPM Report 116 TS EN 61223-3-1 TS EN 60336 TS EN 60601-1-3 TS EN 60601-2-54 TS EN 62220-1 European Commission Radiation Protection No 162




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## Scope of Accreditation

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Certification Sectors		
Inspection Area	Inspection Type	Standard /Specification
Computed Radiography (CR) (Constant, Mobile)	Tube voltage (kVp) Tube output and stability Exposure repeatability and linearity Exposure duration Half value layer and tube filtration Focus point size X-ray - Light field harmony and beam alignment Grid alignment Tube chassis leak radiation Automatic exposure control Detector dose index (DDI) Signal transmission feature DDI repeatability CR image plates compatibility Difference assessment between CR readers 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 quantum efficiency (DQE)	IPEM Report 32 IPEM Report 91 AAPM Report 74 AAPM Report 116 TS EN 61223-3-1 TS EN 60336 TS EN 60601-1-3 TS EN 60601-2-54 TS EN 62220-1 European Commission Radiation Protection No 162




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

## Scope of Accreditation

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<b>Certification Sectors</b>		
<b>Inspection Area</b>	<b>Inspection Type</b>	<b>Standard /Specification</b>
<b>Film-Display Radiography (Constant, Mobile)</b>	Tube voltage (kVp)	IPEM Report 32
	Tube output and stability	IPEM Report 91
	Exposure repeatability and linearity	AAPM Report 74
	Exposure duration	TS EN 61223-3-1
	Half value layer and tube filtration	TS EN 60336
	Focus point size	TS EN 60601-1-3
	X-ray - Light field harmony and beam alignment	TS EN 60601-2-54
	Grid alignment	European Commission Radiation Protection No 162
	Tube chassis leak radiation	
	Automatic exposure control	




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




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



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



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