



NATIONAL ACCREDITATION CENTER
ACCREDITATION CERTIFICATE

TO BE ACTIVE AS TESTING LABORATORY,

ATA KALİBRASYON SAN. ve TİC. LTD. ŞTİ.
ŞERİFALİ MAH. EDEP SOK. NO:45 Y.DUDULLU ÜMRANIYE 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 17025: 2017 General requirements for the competence of testing and calibration laboratories standard.

Accreditation Number : NAC-010-TL
Accreditation Date : 15.01.2021

This certificate is valid until 15.01.2022, 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 17025: 2017 General requirements for the competence of testing and calibration laboratories standard.




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.

Gaynor
GENERAL SECRETARY

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	NAC ACCREDITATION NUMBER	NAC-010-TL
	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	15.01.2021
	ACCREDITATION STANDARD	ISO/IEC 17025:2017

Accreditation Area	General requirements for the competence of testing and calibration laboratories	
Accreditation Standard	ISO/IEC 17025:2017	
Certification Sectors		
Test material/ Products	Test Name	Test Method (National-International standards in-House methods)
Medical Electrical Units - Safety and Performance Tests of all biomedical devices with mains voltage and earth protection	Voltage in Application Parts RMS Chassis Voltage DC Chassis Voltage Protective Earth Resistance Earth Leakage Current Chassis Leakage Current Patient Leakage Current Patient Auxiliary Current Patient Insulation	TS EN 60601-1 TS EN 62353
Defibrillators Safety and Performance Tests	ECG Pulse Test ECG Amplitude Test ECG Frequency Test ECG Arrythmia Test Energy Test (@ 25 to 200 OHM) Charge Time (Battery) Test Synchronized Discharge Test	TS EN 60601-2-27 TS EN 60601-2-4
Physical Therapy Ultrasounds Safety and Performance Tests	Performance Tests	TS EN 60601-2-5




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Accreditation Standard		ISO/IEC 17025:2017
Certification Sectors		
Test material/ Products	Test Name	Test Method (National-International standards in-House methods)
EEG Devices Safety and Performance Tests	Basic Sensitivity Test Step Sensitivity Test Amplitude Linearity Test Frequency Response Test Screen Speed Test Noise Test Connection Accuracy Test General Mode Test Sampling Rate Test	TS EN 60601-2-26
EMG - EP Devices Safety and Performance Tests	Basic Sensitivity Test Noise Test Frequency Response Test Repeatability Test Marker Control Test	TS EN 60601-2-40
Analogue Sphygmomanometers Safety and Performance Tests	System Leak Test Manometer Accuracy Test	TS EN 1060




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Certification Sectors		
Test material/ Products	Test Name	Test Method (National-International standards in-House methods)
Audiometer Device Performance Tests	Frequency of Test Signals Sound Pressure Level (Devices Transmitting by Airway) Vibration Force Level (Devices Transmitting Through Bone Path) Total Harmonic Distortion	TS EN ISO 8253-1
Tympanometer Device Performance Tests	Frequency of Test Signals Sound Pressure Level (Devices Transmitting by Airway) Vibration Force Level (Devices Transmitting Through Bone Path) Total Harmonic Distortion Impedance / Admittance Indicator	TS EN ISO 8253-1 TS EN 60645-5
Test Chamber Performance Tests (Cabinet Audiology)	Lowest Hearing Threshold Level Two Test Tones Measurement (Bone Conduction) Three Test Tones Frequency Change (For Air Conduction) Two Test Tones Frequency Change (For Bone Conduction)	TS EN 8253-1




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Certification Sectors		
Test material/ Products	Test Name	Test Method (National-International standards in-House methods)
Medical & Surgical Face Masks	Bacterial Filtration Efficiency (BFE) Viral Filtration Efficiency (VFE)	EN 14683:2019+AC:2019 Annex B
	Breathing Resistance (Delta P)	EN 14683:2019+AC:2019 Annex C
	Splash Resistance	ISO 22609:2004
	Microbial Cleanliness	EN ISO 11737-1:2018
EN 14683:2019+AC:2019-Medical face masks - Requirements and test methods		



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Certification Sectors		
<i>Test material/ Products</i>	<i>Test Name</i>	<i>Test Method (National-International standards in-House methods)</i>
Respiratory Masks	Penetration of Sodium Chloride	EN 13274-7:2019 + EN 149:2001 + A1:2009 clause 7.9.2
	Penetration of Paraffin Oil	EN 13274-7:2019 + EN 149:2001 + A1:2009 clause 7.9.2
	Breathing resistance	EN 13274-3:2001 + EN 149:2001 + A1:2009 clause 7.16
	Flammability	EN 13274-4:2001 + EN 149:2001 + A1:2009 clause 7.11/8.6
	Exhalation valve pull	EN 149:2001 + A1:2009 clause 7.15
	Exhalation valve flow	EN 149:2001 + A1:2009 clause 7.15
	Practical performance test	EN 13274-2:2019 + EN 149:2001 + A1:2009 clause 7.7
EN 149:2001 + A1:2009- Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking		




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Certification Sectors		
Test material/ Products	Test Name	Test Method (National-International standards in- House methods)
Respiratory Masks	Total inward leakage	EN 13274-1:2001 + EN 149:2001 + A1:2009 clause 7.9.1
	Carbon dioxide content of the inhalation air	EN 13274-6:2001 + EN 149:2001 + A1:2009 clause 7.12/8.7
	Temperature conditioning	EN 13274-5:2001 + EN 149:2001 + A1:2009 clause 8.3.2
	Mechanical strength	EN 149:2001 + A1:2009 clause 8.3.3
	Simulated wearing treatment	EN 149:2001 + A1:2009 clause 8.3.1
	Resistance against penetration by synthetic blood	ISO 22609
EN 149:2001 + A1:2009- Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking		




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Certification Sectors		
Test material/ Products	Test Name	Test Method (National-International standards in- House methods)
Textile	Waterproofing Determination Hydrostatic Pressure Determination	TS EN ISO 811
	Determination of Air Permeability in Fabrics	TS 391 EN ISO 9237
	Abrasion resistance of protective clothing material	TS EN 530
	Determination of resistance to surface wetting (spray test)	TS EN ISO 4920
	Bursting properties of fabrics - Part 2: Pneumatic method for determination of bursting strength and bursting distension	TS EN ISO 13938-2




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Certification Sectors		
Test material/ Products	Test Name	Test Method (National- International standards in- House methods)
Textile	Bursting properties of fabrics Part 1: Hydraulic method for determination of bursting strength and bursting distension	TS 393 EN ISO 13938-1
	Test Methods For Nonwovens Part 3- Determination Of Tensile Strength And Elongation	TS EN 29073-3
	Microbial penetration DRY	EN ISO 22612
	Microbial penetration WET	EN ISO 22610
	Cleanliness microbial / Bioburden	EN ISO 11737-1
	Particle release	EN ISO 9073-10
	Flammability Test	16 CRF Part 1610 ASTM D 1230 TS 6344




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Certification Sectors		
Test material/ Products	Test Name	Test Method (National-International standards in- House methods)
Medical& Surgical Face Mask	Bacterial Filtration Efficiency BFE Viral Filtration Efficiency VFE Breathing Resistance (Delta P)	EN 14683: 2019 + AC2019 Annex B ASTM F 2101-14 EN 14683: 2019 + AC2019 Annex C MIL-M 36954C
	Splash Resistance	ISO 22609: 2004 ASTM F 1862
	Microbial Cleanliness Sub-Micron Particulate Filtration Efeciency PFE Flammability Test	EN ISO 11737-1 2018 ASTM 2299-3 16 CRF Part 1610
Medical& Surgical Grownes and Drapes	Microbial Penetration Resistance (Wet) Microbial Penetration Resistance (Dry) Microbial Evaluation (Bioburden) Particle Evaluation Liquid Penetration Resistance Burst Strength Tensile Strength Impact Penetration Test Ethylene Oxide (EO) Residual Analysis	ISO 22610:2018 ISO 22612:2005 ISO 11737-1:2018 (Bioburden Method) EN ISO 9073-10:2004 EN ISO 811:2018 AATCC 127 EN ISO 13938-1:2019 EN 29073-3:1992 AATCC 42 ISO 10993-7: 2008/AMD 1:2019



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Certification Sectors		
<i>Test material/ Products</i>	<i>Test Name</i>	<i>Test Method (National-International standards in- House methods)</i>
Protective Clothing Against Liquid Chemicals (Type 6)	Abrasion (Martindale)	EN 530:2011 Met. 2 + EN 14325:2018 Par. 4.4.1 + EN 13034+A1:2011 Par. 4.1
	Tearing Strenght. Trapezoid Method	EN ISO 9073-4:199+ EN 14325:2018 Par. 4.7 + EN 13034+A1:2011 Par. 4.1
	Tearing Strenght. Tensile Strenght and elongation. Strip Method	EN ISO 13934-1:2013 + EN 14325:2018 Par. 4.9 + EN 13034+A1:2011 par. 4.1
	Perforation	EN 863:1997 + EN 14325:2018 Par. 4.10 + EN 13034+A1:2011 Par. 4.1
	Permeation By Liquids	EN ISO 6530:2005 + EN 14325:2018 Par. 4.12 and 4.13 + EN 13034+A1:2011 Par. 4.1
	Synthetic Blood	ISO16603 2004) (EN 14126 2003 AC 2004 A 1 A 1) EN 1149-5:2018 EN 1149-1 2006 EN 1149-3 2004 Met.2
	Protective Clothing Electrostatic Properties Material Performance and Desing Requirements	EN ISO 13935-2:2014 + EN 14325:2018 Par. 5.5 + EN 13034+A1:2011 Par. 4.2.2
	Seam Tensile Properties. Grab Method	EN ISO 17491-4:2008/AMD 1:2016 + EN 13034:2009 Par. 5.2
Penetration By Spray		




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Certification Sectors		
<i>Test material/ Products</i>	<i>Test Name</i>	<i>Test Method (National-International standards in- House methods)</i>
Protective Clothing For Use Against Solid Particulates (Type 5)	Abrasion (Martindale)	EN 530:2011 Met. 2 + EN 14325:2018 Par. 4.4.1 + EN ISO 13982-1:2004/AMD 1:2010 Par. 4.1
	Resistance To Damage By Repeated Flexing	EN ISO 7854:1999 Met. B + EN 14325:2018 Par. 4.5 + EN ISO13982-1:2004/AMD 1:2010 Par. 4.1
	Tearing Strenght. Trapezoid Method	EN ISO 9073-4:1999 + EN 14325:2018 Par. 4.7 + EN ISO 13982-1:2004/AMD 1:2010 Par. 4.1
	Perforation	EN 863:1997 + EN 14325:2018 Par. 4.10 + EN 13982-1 :2004/AMD 1:2010 Par. 4.1
	Synthetic Blood	ISO16603 2004) (EN 14126 2003 AC 2004 4.1.4.1) ISO 16604
	Protective Clothing Electrostatic Properties Material Performance and Desing Requirements	EN 1149-5:2018 EN 1149-1 2006 EN 1149-3 2004 Met.2
	Seam Tensile Properties. Grab Method	EN ISO 13935-2:2014 + EN 14325:2018 Par. 5.5 + EN ISO 13982-1:2004/AMD 1:2010 Par. 4.2.2
Aerosol Penetration	EN ISO 13982-1:2004/AMD 1:2010 Par. 4.3.2	



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Certification Sectors		
Test material/ Products	Test Name	Test Method (National-International standards in- House methods)
Protective Clothing Against Liquid Chemicals - Performance Requirements For Clothing With Liquid-tight (Type 3) or Spray-tight (Type 4) Connections	Abrasion (Martindale)	EN 530:2011 Met. 2 + EN 14325:2018 Par. 4.4.1 + EN 14605:2009 Par. 4.1
	Resistance To Damage By Repeated Flexing	EN ISO 7854:1999 Met. B + EN 14325:2018 Par. 4.5 + EN 14605:2009 Par. 4.1
	Tearing Strenght. Trapezoid Method	EN ISO 9073-4:1999 + EN 14325:2018 Par. 4.7 + EN 14605:2009 Par. 4.1
	Tensile Strength And Elongation. Strip Method	EN ISO 13934-1:2013 + EN 14325:2018 Par. 4.9 + EN 14605:2009 Par. 4.1
	Perforation	EN 863:1997 + EN 14325:2018 Par. 4.10 + EN 14605: 2009 Par. 4.1
	Permeation By Liquids	EN ISO 6529:2013 + EN 24325:2018 Par. 4.11 + EN 14605:2009 Par. 4.2
	Synthetic Blood	ISO16603 2004) (EN 14126 2003 AC 2004 4.1.4.1) ISO 16604
	Seam Tensile Properties. Grab Method	EN ISO 13935-2:2014 + EN 14325:2018 Par. 5.5 + EN 14605:2009 Par. 4.2
	Penetration By Spray	EN ISO 17491-4:2008/AMD 1:2016 + EN 14605:2009 Par. 4.3.4
	Penetration By a Jet of Liquid	EN ISO 17491-3:2008 + EN 14605:2009 Par. 4.3.4
	Visor. Mechanical Strenght of Visor	EN 12941:2009 + EN 14605:2009 Par. 4.4.2
	Visor. Field of Vision	EN 14605:2009 Par. 4.4.3
Visor. Distortion of Vision	EN 14605:2009 Par. 4.4.4	



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Certification Sectors		
Test material/ Products	Test Name	Test Method (National-International standards in- House methods)
Protective Clothing Against Liquid and Gaseous Chemicals, Including Liquid Aerosols and Solid Particles Gas-Tight (Type 1) and "non-gas-tight" (Type 2)	Abrasion (Martindale)	EN 530:2011 Met. 2 + EN 943-1:2015 +A1:2019 Appendix B.2.3
	Resistance To Damage By Repeated Flexing	EN ISO 7854:1999 Met. B + EN 943-1:2005 +A1:2019 Appendix B.2.4
	Tearing Strenght. Trapezoid Method	EN ISO 9073-4:1999 + EN 943-1:2015 + A1:2019 Appendix B.2.6
	Tensile Strength And Elongation. Strip Method	EN ISO 13934-1:2013 + EN 943-1:2015 + A1:2019 Appendix B.2.8
	Perforation	EN 863:1997 + EN 943-1:2015+A1:2019 Appendix B.2.9
	Synthetic Blood	ISO16603 2004) (EN 14126 2003 AC 2004 4.1.4.1) ISO 16604
	Permeation By Liquids	EN ISO 6592:2013 + EN 943-1:2015 + A1:2019 Appendix B.2.10
	Ignition And Flammability	EN 13274-4:2002 Met.3 + EN 943-1:2015 + A1:2019 Appendix B.2.13
	Seam Tensile Properties. Grab Method	EN ISO 13935-2:2014 + EN 943-1:2015 + A1:2019 Appendix B.3.5
	Resistance of Joints and Assemblies	EN 943-1:2015 + A1:2019 Par. 6.5
	Practical Performance Tests. Simulation Test to Work	EN 943-1:2015 + A1:2019 Par. 5.2
Conditioning	EN 943-1:2015 + A1:2019 Par. 5.2	



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Certification Sectors		
Test material/ Products	Test Name	Test Method (National-International standards in- House methods)
Protective Clothing Against Liquid and Gaseous Chemicals, Including Liquid Aerosols and Solid Particles Gas-Tight (Type 1) and "non-gas-tight" (Type 2)	Conditioning	EN 943-1:2015 + A1:2019 Par. 5.2
	Determination of Leak-Tightness os Gastight Suits	EN 464:1995 + EN 943-1:2015+A1:2019 Par. 5.3
	Leak Tightness of Gas Internal Pressure	EN 943-1:2015 + A1:2019 Appendix A
	Visual Screen. Mechanical Resistance	EN 943-1:2015 + A1:2019 Par. 6.7
	Resistance of the Connection System Air Supply	EN 14594:2018 + EN 943-1:2015+ A1:2019 Par. 5.7.1
	Resistance to Bending	EN 14594:2018 + EN 943-1:2015+ A1:2019 Par. 5.7.3
	Practical Performance Tests. Pairs. Resistance of the Connections. Airflow	EN 14594:2018 + EN 943-1:2015+ A1:2019 Par. 5.8.1, 5.8.2, 5.10
	Breathing Hose Outside	EN 14594:2018 + EN 943-1:2015+ A1:2019 Par. 5.9.1
	Breathing Hose Resistant to External Collapse	EN 14594:2018 + EN 943-1:2015+ A1:2019 Par. 5.9.1.1
	Breathing Hose Internal	EN 14594:2018 + EN 943-1:2015+ A1:2019 Par. 5.9.2
	Breathing Hose Resistant to Internal Collapse	EN 14594:2018 + EN 943-1:2015+ A1:2019 Par. 5.9.2.1
Ventilation Hose Outside	EN 14594:2018 + EN 943-1:2015+ A1:2019 Par.5.9.3	




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Accreditation Area	General requirements for the competence of testing and calibration laboratories
Accreditation Standard	ISO/IEC 17025:2017

Certification Sectors		
Test material/ Products	Test Name	Test Method (National-International standards in- House methods)
Protective Clothing Against Liquid and Gaseous Chemicals, Including Liquid Aerosols and Solid Particles Gas-Tight (Type 1) and "non-gas-tight" (Type 2)	Air Flow Rate Warning Device	EN 14594:2018 + EN 943-1:2015+ A1:2019 Par. 5.11
	Discharge Devices, Tightness Test to Losses For Exhalation Valves	EN 943-1:2015 + A1:2019 Par. 5.13 and 6.6
	Pressure in the Chemical Protective Coverall	EN 943-1:2015 + A1:2019 Par. 5.14 and 6.4
	Breathing Resistance	EN 943-1:2015 + A1:2019 Par. 5.15
	Carbon Dioxide Content of Exhalation Air	EN 943-1:2015 + A1:2019 Par. 5.16
	Noise Associated With The Feeding of Air Into the Suit	EN 943-1:2015 + A1:2019 Par. 5.17
	Visor. Field of Vision	EN 943-1:2015 + A1:2019 Par. 5.5.3
	Visor. Distortion of Vision	EN 943-1:2015 + A1:2019 Par. 5.5.2



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SCOPE OF ACCREDITATION

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	NAC ACCREDITATION NUMBER	NAC-010-TL
	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	15.01.2021
	ACCREDITATION STANDARD	ISO/IEC 17025:2017

Accreditation Area	General requirements for the competence of testing and calibration laboratories
Accreditation Standard	ISO/IEC 17025:2017

Certification Sectors		
Test material/ Products	Test Name	Test Method (National-International standards in- House methods)
Protective Clothing Against Biological Risk	Abrasion (Martindale)	EN 530:2011 Met. 2 + EN 14325:2018 Par. 4.4.1 + EN 14126:2004 Par. 4.1.2
	Tearing Strenght. Trapezoid Method	EN ISO 9073-4:1999 + EN 14325:2018 Par. 4.7 + EN 14126:2004 Par. 4.1.2
	Resistance To Damage By Repeated Flexing	EN ISO 7854:1999 Met. B + EN 14325:2018 Par. 4.5 + EN 14126:2004 par. 4.1.2
	Burst Strength and Bursting Distension	EN ISO 13938-1:2001 + EC 1-2004 + EN 14325:2018 Par. 4.8 + EN 14126:2004 Par. 4.1.2
	Tensile Strenght. Strip Method	EN ISO 13934-1:2013 + EN 14325:2018 Par. 4.9 + EN 14126:2004 Par. 4.1.2
	Perforation	EN 863:1997 + EN 14325:2018 Par. 4.10 + EN 14126:2004 Par. 4.1.2
	Ignition And Flammability	EN 13274-4:2002 Met.3 + EN 14325:2018 Par. 4.14 and 4.15 + EN 14126:2004 Par. 4.1.2




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Accreditation Area	General requirements for the competence of testing and calibration laboratories
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Certification Sectors

<i>Test material/ Products</i>	<i>Test Name</i>	<i>Test Method (National-International standards in- House methods)</i>
Medical gloves for single use	Requirements and testing for freedom from holes	TS EN 455-1 / ASTM D 6319
	Requirements and testing for physical properties	TS EN 455-2 / ASTM D 6319 / ASTM D 5151-06
	Requirements and testing for biological evaluation	TS EN 455-3
	Requirements and testing for shelf life determination	TS EN 455-4 / ASTM D 6319
	Determination of resistance to degradation by chemicals	TS EN 374-3 / TS EN 374-4
	Terminology and performance requirements for micro-organisms risks	TS EN 374-2 / TS EN 374-5




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Attachment of Accreditation Certificate SCOPE OF ACCREDITATION

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 TESTING LABORATORY ISO/IEC 17025:2017 NAC-010-TL	NAC ACCREDITATION NUMBER	NAC-010-TL
	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	15.01.2021
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Accreditation Area	General requirements for the competence of testing and calibration laboratories
Accreditation Standard	ISO/IEC 17025:2017

Certification Sectors

<i>Test material/ Products</i>	<i>Test Name</i>	<i>Test Method (National-International standards in- House methods)</i>
Medical gloves for single use	☐ Standard Specification for Rubber Examination Gloves	ASTM D3578 - 05
	Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs	☐ ASTM D6978 - 05
	☐ Standard Test Method for Residual Powder on Medical Gloves	ASTMD 6124-06
Medical Electrical Equipment	General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	EN 60601-1-8



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