



TURKISH ACCREDITATION AGENCY

## ACCREDITATION CERTIFICATE

As a "Type A" Inspection Body

**EGE NİSAN TEMİZ ODA HİJYENİK HAV. SİST. TEST VE DOĞRULAMA HİZM. TİCARET LİMİTED ŞİRKETİ**

Central Address: BARIŞ MAH. ADA ÇİFTLİĞİ CAD. SEVDA APARTMANI NO:7/1 BEYLİKDÜZÜ İstanbul / Türkiye

*\*The list of the branches operating under the same accreditation depending on the central address and the scope of these branches are given in the annexes.*

is accredited in accordance with TS EN ISO/IEC 17020:2012 standard within the scope given in Annex following the assessment conducted by TURKAK.

**Accreditation Number : AB-0111-M**

**Accreditation Date : 03.10.2011**

**Revision Date / Number : 01.05.2024 / 14**

This certificate shall remain in force until **31.01.2028**, subject to continuing compliance with the standard **TS EN ISO/IEC 17020:2012**, related regulations and requirements.

Gülden Banu Müderrisoğlu  
Secretary General



Turkish Accreditation Agency (TURKAK) is a signatory to the European co-operation for Accreditation (EA) Multilateral Agreement (MLA) and International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Agreement (MRA) in the scope of ISO/IEC 17020.

*This document has been signed by Gülden Banu Müderrisoğlu with a secure electronic signature in accordance with the electronic signature law numbered 5070. Use the QR code to verify the e-signed document.*

 <p><b>TÜRKAK</b></p> <p>Inspection TS EN ISO/IEC 17020 AB-0111-M</p>	<p><b>EGE NİSAN TEMİZ ODA HİJYENİK HAV. SİST. TEST VE DOĞRULAMA HİZM. TİCARET LİMİTED ŞİRKETİ</b></p> <p>Accreditation Nr: AB-0111-M Revision Nr: 14 Date: 01.05.2024</p>	
	<p>"Type A" Inspection Body</p> <p>Address : BARIŞ MAH. ADA ÇİFTLİĞİ CAD. SEVDA APARTMANI NO:7/1 BEYLİKDÜZÜ İstanbul / Türkiye</p> <p>Phone : +90 212 220 8062 Fax : Email : info@egenisan.com Website : www.egenisan.com</p>	

**Clean Rooms, Related Controlled Environments and Air Conditioning Systems**

Inspection Field	Inspection Type	Standard/Specification
<p>Bio-Safety Cabins</p> <p>Air Velocity Measurement Incoming Air Flow Rate Measurement HEPA and ULPA Filter Leakage Measurement Air Flow Direction and Visualization Measurement Control of Alarm and Other Functions</p>	<p>Initial Inspection Periodic Inspection</p>	<p>TS EN 12469 ANSI/NSF-49 IEST-RP-CC034</p>
<p>Laminar Airflow Cabinets</p> <p>Air Velocity Measurement HEPA and ULPA Filter Leakage Measurement Air Flow Direction and Visualization Measurement Particle Counting Measurement</p>	<p>Initial Inspection Periodic Inspection</p>	<p>TS EN ISO 14644-1 TS EN ISO 14644-2 TS EN ISO 14644-3 IEST-RP-CC006 IEST-RP-CC034 IEST-RP-CC002</p>
<p>Ventilation and Air Conditioning Systems Metal Air Ducts with Rectangular Section Circular Sheet Metal Ducts</p>	<p>Initial Inspection</p>	<p>TS EN 1507 TS EN 12237 ANSI/SMACNA-016 BESA/DW 143</p>
<p>16.2 HVAC Systems of Production Areas, Laboratories and Laminar Air Flow Areas</p> <ul style="list-style-type: none"> <li>- Airflow Test (Flow, Velocity and Uniformity)</li> <li>- Air Pressure Difference Test</li> <li>- Installed Filter (HEPA and ULPA) System Leakage Tests</li> <li>- Particle Count and Classification of Air Cleanliness</li> <li>- Temperature and Humidity Test</li> <li>- Airflow Direction Test and Visualization</li> <li>- Recovery Time</li> </ul>	<p>Initial Inspection Periodic Inspection</p>	<p>EudraLex - Volume 4 Annex 1 Good Manufacturing Practice (GMP) for Medicinal Products for Human and Veterinary Use FDA cGMP - Sterile Drug Products Produced by Aseptic Processing ISO 14644-1 ISO 14644-2 ISO 14644-3 IEST-RP-CC006 IEST-RP-CC034</p>
<p>16.1. HVAC Systems of Operating Rooms, Intensive Care Units and Other Hospital Hygienic Areas</p> <ul style="list-style-type: none"> <li>- Airflow Test (Flow, Velocity and Uniformity)</li> <li>- Air Pressure Difference Test</li> <li>- Installed Filter (HEPA and ULPA) System Leakage Tests</li> <li>- Particle Count and Classification of Air Cleanliness</li> <li>- Temperature and Humidity Test</li> <li>- Airflow Direction Test and Visualization</li> <li>- Recovery Time</li> <li>- Determining The Degree of Protection or Measuring Turbulence Intensity</li> </ul>	<p>Initial Inspection Periodic Inspection</p>	<p>DIN 1946-4 ISO 14644-1 ISO 14644-2 ISO 14644-3 IEST-RP-CC006 IEST-RP-CC034 ASHRAE 170</p>



 <p>Inspection TS EN ISO/IEC 17020 AB-0111-M</p>	<b>EGE NİSAN TEMİZ ODA HİJYENİK HAVALANDIRMA SİSTEMLERİ DOĞRULAMA HİZMETLERİ TİCARET LTD. - İZMİR ŞUBE</b>	
	Accreditation Nr: AB-0111-M Revision Nr: 14 Date: 01.05.2024	
"Type A" Inspection Body		
Address : GAZİ MAHALLESİ HASAN GÜVEN CADDESİ NO:148 D BLOK GAZİEMİR-İZMİR İzmir/Türkiye	Phone : +90 232 220 8078 Fax : Email : infoizmir@egenisan.com Website :	

Clean Rooms, Related Controlled Environments and Air Conditioning Systems

Inspection Field	Inspection Type	Standard/Specification
Bio-Safety Cabins Air Velocity Measurement Incoming Air Flow Rate Measurement HEPA and ULPA Filter Leakage Measurement Air Flow Direction and Visualization Measurement Control of Alarm and Other Functions	Initial Inspection Periodic Inspection	TS EN 12469 ANSI/NSF-49 IEST-RP-CC034
Laminar Airflow Cabinets Air Velocity Measurement HEPA and ULPA Filter Leakage Measurement Air Flow Direction and Visualization Measurement Particle Counting Measurement	Initial Inspection Periodic Inspection	TS EN ISO 14644-1 TS EN ISO 14644-2 TS EN ISO 14644-3 IEST-RP-CC006 IEST-RP-CC034 IEST-RP-CC002
Ventilation and Air Conditioning Systems Metal Air Ducts with Rectangular Section Circular Sheet Metal Ducts	Initial Inspection	TS EN 1507 TS EN 12237 ANSI/SMACNA-016 BESA/DW 143
16.2 HVAC Systems of Production Areas, Laboratories and Laminar Air Flow Areas - Airflow Test (Flow, Velocity and Uniformity) - Air Pressure Difference Test - Installed Filter (HEPA and ULPA) System Leakage Tests - Particle Count and Classification of Air Cleanliness - Temperature and Humidity Test - Airflow Direction Test and Visualization - Recovery Time	Initial Inspection Periodic Inspection	EudraLex - Volume 4 Annex 1 Good Manufacturing Practice (GMP) for Medicinal Products for Human and Veterinary Use FDA cGMP - Sterile Drug Products Produced by Aseptic Processing ISO 14644-1 ISO 14644-2 ISO 14644-3 IEST-RP-CC006 IEST-RP-CC034
16.1. HVAC Systems of Operating Rooms, Intensive Care Units and Other Hospital Hygienic Areas - Airflow Test (Flow, Velocity and Uniformity) - Air Pressure Difference Test - Installed Filter (HEPA and ULPA) System Leakage Tests - Particle Count and Classification of Air Cleanliness - Temperature and Humidity Test - Airflow Direction Test and Visualization - Recovery Time Determining The Degree of Protection or Measuring Turbulence Intensity	Initial Inspection Periodic Inspection	DIN 1946-4 ISO 14644-1 ISO 14644-2 ISO 14644-3 IEST-RP-CC006 IEST-RP-CC034 ASHRAE 170

