



INTERNATIONAL ACCREDITATION KEEP SERVICE

ACCREDITATION CERTIFICATE

BEYAZ HAVA MÜHENDİSLİK TEST KONTROL HİZMETLERİ TİC.LTD.ŞTİ.

FATİH MAH. GEYLANI CAD. NO:6/A SANCAKTEPE / İSTANBUL / TURKEY

As a result of the audit conducted by the IAKS, it is accredited in the annexes to the ISO /IEC 17020:2012 General requirements for the competence of testing and calibration laboratories standard,

Accreditation Number: IAKS-TL-1085

Accreditation Date: 30.04.2024

This certificate is valid until 30.04.2025, if the above mentioned name and address continue to comply with the relevant standards, international and regional rules in addition to the written organizations ISO/IEC 17020:2012 Examination

This certificate is given by IAKS. The certificate becomes invalid in case of suspension and cancellation of accreditation.


For current accreditation information visit www.iaks.us or communicate with IAKS on info@iaks.us

A handwritten signature in blue ink, appearing to be 'S. Yılmaz', is written over the word 'CONFIRMATION'.

CONFIRMATION

Attachment of Accreditation certificate

SCOPE OF ACCREDITATION


| | | |
|--|-------------------------------|---|
|  <p>EXAMINATION ISO/IEC 17020-1:2012 IAKS-EX-1014</p> | IAKS ACCREDITED NUMBER | IAKS-MS-1085 |
| | COMPANY NAME | BEYAZ HAVA MÜHENDİSLİK TEST KONTROL HİZMETLERİ TİC.LTD.ŞTİ. |
| | ADRESS | FATİH MAH. GEYLANİ CAD. NO:6/A SANCAKTEPE / İSTANBUL |
| | CONTACT NAME | |
| | TELEPHONE | |
| | ACCREDITATION DATE | 30.04.2024 |
| | ACCREDITATION STANDARD | ISO/IEC 17020:2012 |

| | |
|--------------------------------|---|
| ACCREDITATION AREA: | General requirements for the competence of testing and calibration laboratories |
| ACCREDITATION STANDARD: | ISO/IEC 17020:2012 |

| Inspection Area | Examination Type | Standard / Specification |
|---|--|---|
| PHARMACEUTICALS AND MEDICAL DEVICES -MATERIAL PRODUCTION AREAS OPERATING THEATRES INTENSIVE CARE UNITS FOOD PRODUCTION AREAS MICRO ELECTRONIC PART PRODUCTION AREAS OTHER AREAS USING CLEAN and/or HYGIENIC ROOMS LAMİNAR AIR FLOW CLEAN ROOM/DEVICES | HVAC SYSTEM OPERATION / PERFORMANCE CHARACTERISATION (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-GMP -EUDRALEX Volume 4 :Annex 1:2008- GMP Human and Medicinal Products Veterinary Use -FDA cGMP: 2004-Sterile Pharmaceutical Products Manufactured by Aseptic Process -T.C.S.B - PRIVATE HOSPITALS REGULATION -Quality Standards in Health |
| | MEASUREMENT OF AIR FLOW, AIR VELOCITY AND UNIFORMITY | IEST-RP-CC006.3 ISO 14644-2 ISO 14644-3 DIN 1946-4 |

Attachment of Accreditation certificate


SCOPE OF ACCREDITATION

| | | |
|--|-------------------------------|---|
|  <p>EXAMINATION ISO/IEC 17020-1:2012 IAKS-EX-1014</p> | IAKS ACCREDITED NUMBER | IAKS-MS-1085 |
| | COMPANY NAME | BEYAZ HAVA MÜHENDİSLİK TEST KONTROL HİZMETLERİ TİC.LTD.ŞTİ. |
| | ADRESS | FATİH MAH. GEYLANI CAD. NO:6/A SANCAKTEPE / İSTANBUL |
| | CONTACT NAME | |
| | TELEPHONE | |
| | ACCREDITATION DATE | 30.04.2024 |
| | ACCREDITATION STANDARD | ISO/IEC 17020:2012 |

| Inspection Area | Examination Type | Standard / Specification |
|---|---|--|
| PRODUCTION AREAS OF PHARMACEUTICALS AND MEDICAL DEVICES/MATERIALS | HEPA and ULPA FILTER EQUIPMENT SEALING TEST | IEST-RP-CC034.3 IEST-RP-CC006.3 ISO 14644-2 ISO 14644-3 DİN 1946-4 |
| OPERATING THEATRES | | |
| INTENSIVE CARE UNITS FOOD | PARTY ASH COUNT and CLEAN ROOM CLASSIFICATION | IEST-RP-CC006.3 ISO 14644-1. ISO 14644-2 DİN 1946-4 |
| PRODUCTION AREAS | | |
| MICRO ELECTRONIC PART PRODUCTION AREAS | MEASUREMENT OF PRESSURE DIFFERENCE | IEST-RP-CC006.3 ISO 14644-2 ISO 14644-3 DİN 1946-4 |
| OTHER AREAS USING CLEAN and/or HYGIENIC ROOMS | | |
| LAMİNAR AIR FLOW CLEAN ROOM/ DEVICES | TEMPERATURE AND HUMİDİTY MEASUREMENT | IEST-RP-CC006.3 ISO 14644-3 DİN 1946-4 |

Attachment of Accreditation certificate


SCOPE OF ACCREDITATION

| | | |
|--|-------------------------------|---|
|  <p>EXAMINATION ISO/IEC 17020-1:2012 IAKS-EX-1014</p> | IAKS ACCREDITED NUMBER | IAKS-MS-1085 |
| | COMPANY NAME | BEYAZ HAVA MÜHENDİSLİK TEST KONTROL HİZMETLERİ TİC.LTD.ŞTİ. |
| | ADRESS | FATİH MAH. GEYLANİ CAD. NO:6/A SANCAKTEPE / İSTANBUL |
| | CONTACT NAME | |
| | TELEPHONE | |
| | ACCREDITATION DATE | 30.04.2024 |
| | ACCREDITATION STANDARD | ISO/IEC 17020:2012 |

| Inspection Area | Examination Type | Standard / Specification |
|---|--|---|
| PRODUCTION AREAS OF PHARMACEUTICALS AND MEDICAL DEVICES/MATERIALS OPERATING THEATRES INTENSIVE CARE UNITS FOOD PRODUCTION AREAS MICRO ELECTRONIC PART PRODUCTION AREAS OTHER AREAS USING CLEAN and/or HYGIENIC ROOMS LAMİNAR AIR FLOW CLEAN ROOM/ DEVICES | TEST FOR VISUALISATION OF AIR FLOW CHARACTERISTICS | IEST-RP-CC006.3 ISO 14644-2 ISO 14644-3 DİN 1946-4 |
| | DETERMINATION OF DECONTAMINATION/RECOVERY TIME | IEST-RP-CC006.3 14644-2 ISO 14644-3 DİN 1946-4 |
| | MEASURING THE LEAK TIGHTNESS OF THE CLEAN ROOM | ISO 14644-3 DİN 1946-4 |

Attachment of Accreditation certificate

SCOPE OF ACCREDITATION

| | | |
|--|-------------------------------|---|
|  <p>EXAMINATION ISO/IEC 17020-1:2012 IAKS-EX-1014</p> | IAKS ACCREDITED NUMBER | IAKS-MS-1085 |
| | COMPANY NAME | BEYAZ HAVA MÜHENDİSLİK TEST KONTROL HİZMETLERİ TİC.LTD.ŞTİ. |
| | ADRESS | FATİH MAH. GEYLANI CAD. NO:6/A SANCAKTEPE / İSTANBUL |
| | CONTACT NAME | |
| | TELEPHONE | |
| | ACCREDITATION DATE | 30.04.2024 |
| | ACCREDITATION STANDARD | ISO/IEC 17020:2012 |

| Inspection Area | Examination Type | Standard / Specification |
|--|--|---|
| <p>PRODUCTION AREAS OF PHARMACEUTICALS AND MEDICAL DEVICES/MATERIALS</p> <p>OPERATING THEATRES INTENSIVE CARE UNITS FOOD PRODUCTION AREAS MICRO ELECTRONIC PARTS PRODUCTION AREAS</p> <p>OTHER AREAS USING CLEAN and/or HYGIENIC ROOMS</p> <p>LAMINAR AIR FLOW CLEAN ROOM / CLEANROOMS</p> <p>COMFORT ZONES FUME HOODS</p> | <p>HVAC SYSTEM INSTALLATION QUALIFICATION (IQ)</p> <p>TEST OF SEALING AND DURABILITY IN VENTILATION DUCTS</p> <p>-</p> <p>-Rectangular Section Air Ducts -Circular Section Air Ducts</p> | <p>-TS EN 1507 -TS EN 12237 -ANSI/SMACNA-016 -BESA/DW 143</p> |
| <p>BIOSAFETY CABINETS</p> | <p>PERFORMANCE QUALIFICATION (PQ)</p> <p>-FILTER TIGHTNESS TEST -MEASUREMENT OF AIR FLOW RATE -VISUALISATION OF AIR FLOW DIRECTION -CONTROL OF ALARM AND OTHER FUNCTIONS</p> | <p>TS EN 12469 WHOGLP ANSI/NSF 49 TS EN 14175-1 TS EN 14175-2 TS EN 14175-3 TS EN 14175-4 TS EN 14175-6</p> |
| Scope of Test | | |
| A TYPE INSPECTION BODY | | |
| CLEAN ROOMS, RELATED CONTROLLED ENVIRONMENTS AND VENTILATION SYSTEMS | | |