TRUKING

Truking Intelligent Aseptic Isolation Technology

楚天智能无菌隔离技术

www.truking.com

让世界制药工业插上智慧的翅膀

Equip global pharmaceutical manufacturing industry with intelligent wings.

TRUKING

Contents 目录

负压隔离器 - 01 -
Negative Pressure Isolator

过氧化氢传递舱 - 03 -
VHP Pass Box

灭菌柜出料隔离器 - 05 -
Autoclave Unloading Isolator

无菌检查隔离器 - 07 -
Sterility Testing Isolator

原料药隔离器 - 09 -
API Isolator

联动生产隔离系统 - 11 -
Combined Production Isolation System

楚天科技股份有限公司成立于2000年，是中国医药装备行业的领军企业，也是世界医药装备行业的知名企业之一。主营业务系医药装备及其整体技术解决方案，并率先推动智慧医药工厂的研究与开发。公司系中国A股上市公司。旗下拥有德国ROMACO集团、楚天华通、四川省医药设计院、楚天飞云、楚天源创、楚天微球、楚天思优特、楚天思为康、楚天华兴、楚天长兴、楚天科仪、楚天净邦、楚天派特、楚天博源、楚天新材料、楚天智能机器人等十多家全资或控股子公司，全球员工总数9000余人，总资产110亿元。

公司已有长沙和德国两大运营总部，建有长沙中央技术研究院、欧洲技术研究院和四川省医药设计院等研发机构。设有国家级企业技术中心，国家级创新基地，博士后科研工作站，院士专家工作站等多个技术与创新平台。截至2023年12月31日，共提出5466项中国专利申请，授权专利4313项，有效专利3090项。另提出54件PCT国际专利申请，在美国、俄罗斯、印度、韩国、德国、印尼、日本、欧洲等多国获得26项专利授权。牵头制订了本系统国家行业产品技术标准20多项。集团产品与服务已累计覆盖180多个国家和地区，国际市场占有率正逐年快速提升。

Founded in 2000, Truking Technology Limited has become a leading pharmaceutical equipment company in China and renowned worldwide. The company specializes in pharmaceutical equipment and integrated solutions and takes the initiative to push forward the R&D of smart pharmaceutical factories. It is a listed A-share company with multiple wholly-owned or holding subsidiaries, such as Germany-based Romaco Group, Truking Watertown, Sichuan Pharmaceuticals Design Institute, Truking Feiyun, Truking Ingenuity, Truking Micro-Sphere, Truking SUT, Truking Gene, Wachine, Truking Changxing, Truking Scientific Instrument, Truking Jingbang Engineering Technology, Truking Pitide Biotechnology, Truking Boyuan Intelligent Technology, Truking New Material, Truking Intelligent Robot etc. Truking has over 9000 employees around the globe, with a total asset of over 11 billion RMB.

Truking has two operational headquarters in Changsha, China, and Germany, with research and development institutions including Changsha Central Technology Research Institute, Europe Technology Research Institute, and Sichuan Pharmaceuticals Design Institute. It has established many platforms for technology innovation, such as the National Enterprise Technology Center, National Innovation Center, Post-Doctoral Scientific Research Station, and Academician Expert Workstation. By December 31, 2023, a total of 5,466 patent applications from China have been submitted, with 4,313 patents granted and 3,090 patents currently in force. Additionally, 54 PCT international patent applications were filed, resulting in 26 patents granted in multiple countries including the United States, Russia, India, South Korea, Germany, Indonesia, Japan, and Europe. The company has led the development of over 20 national industry product technical standards for this system. The products and services of the group have now reached over 180 countries and regions, with its international market share steadily increasing year by year.

负压隔离器 Negative Pressure Isolator

主要用途 / Main Application

主要用于制药厂粉末类产品的称量、配料、取样、分装、投料等。

It is mainly used for weighing, batching, sampling, packaging and feeding of powder products in pharmaceutical factories.

优势特点 / Main Characteristics and Advantages

- 设备腔体由 SUS316L 不锈钢制成，厚度为 4mm，可视窗采用 10~15mm 钢化玻璃制成；
- 系统符合人机工程学设计，可达到 OEB 5 级（OEL ＜ 1 μg/m^3）防护等级，提供第三方 SMEPAC 测试服务；
- 配备康斐尔 PUSH-PUSH 安全更换型过滤器，可在线更换，确保人员安全；
- 隔离器可在线检测泄漏率（压力衰减法），满足 ISO 10648，ISO14644，PDA TR34 的数据要求；
- 系统设计符合 GMP、ISO、ISPE、药典等相关要求，满足 21CFR Part11，产品通过欧盟 CE 认证；
- 根据工艺需求，可配置在线称重天平，数据可与系统集成或独立；
- 根据工艺需求，可配置 RTP、αβ 分离蝶阀和连续套袋系统；
- 根据工艺需求，可配置过氧化氢灭菌系统，及生物灭活系统；
- 根据工艺需求，可配置氮气系统及响应氧含量检测；
- 根据工艺需求，整机可满足防爆需求。

- The device chamber is made of SUS316L stainless steel with a thickness of 4mm. The visible widown is made of 10~15mm toughened glass.
- The system conforms to ergonomics design, it can reach OEB level 5 (OEL < 1, g/m) protection level and provide third-party SMEPAC test service;
- Equipped with Camfil push-push security change-over filter, it can be replaced online to ensure personnel safety;
- The isolator can detect leakage rate online (pressure attenuation method), which meets the data requirements of ISO 10648, ISO14644 and PDA TR34.
- The system design conforms to GMP, ISO, ISPE, pharmacopoeia and other related requirements, and meets 21CFR Part11. The product has passed the European CE certification.
- According to the process requirements, can be configured online weighing balance, data can be integrated with the system or independent;
- According to the process requirements, can be equipped with RTP, plying separate butterfly valve and continuous bagging system;
- According to process requirements, hydrogen peroxide sterilization system and biological inactivation system can be configured;
- According to the process requirements, the nitrogen system and the response oxygen content can be configured.
- According to the process requirements, the whole machine can meet the explosion-proof requirements;

主要技术参数 / Main Technical Parameters

洁净度等级 Cleanliness Level	泄漏率 Leakage Rate	防护等级 Protection Grade	无菌保证水平 Aseptic Assurance	氧含量 Oxygen Content	噪声 Noise	照度 Intensity of Illumination	压差范围 Differential Pressure Range	裂隙风速 Crack Speed
A 级 A grade	0.5%	OEB 5	SAL ⩽ 10-6	⩽ 3%	⩽ 65dB	⩾ 500lux	-80pa~+80Pa	⩾ 0.5m/s

过氧化氢传递舱 VHP Pass Box

主要用途 / Main Application

过氧化氢传递舱用于物料外表面的低温灭菌，以避免物料从低级别洁净区进入高级别区域带入污染，可用于无菌生产中需要传递的各类清洁和干燥的物品。

VHP pass box is used for low-temperature sterilization of the material surface to avoid contamination of the material from the low-grade clean area to the high-level area. It can be used for all kinds of clean and dry articles that need to be delivered in aseptic production.

优势特点 / Main Characteristics and Advantages

- 设备腔体由 SUS316L 不锈钢制成，厚度为 3mm，可视窗采用 15mm 钢化玻璃制成；
- 系统集成过氧化氢灭菌器，可在线灭菌；
- 传递舱内部为单向气流送风，可竖直单向流或水平单向流；
- 系统符合人机工程学设计，洁净度为 ISO 4.8，提供全套 4Q 验证服务；
- 系统可在线检测泄漏率（压力衰减法），满足 ISO 10648，ISO14644，PDA TR34 的数据要求；
- 系统设计符合 GMP、ISO、ISPE、药典等相关要求，满足 21CFR Part11，产品通过欧盟 CE 认证。

+ The chamber is made of SUS316L stainless steel with a thickness of 3mm. The visible window is made of 15mm toughened glass.
+ System integrated hydrogen peroxide sterilizer, online sterilization is available.
+ One-way air supply is provided inside the pass box, which can flow vertically or horizontally.
+ The system conforms to ergonomic design, the cleanliness is ISO 4.8, and a full set of 4Q verification service can be provided;
+ The system can detect leakage rate online (pressure attenuation method), meeting the data requirements of ISO 10648, ISO14644, PDA TR34;
+ The system design conforms to GMP, ISO, ISPE, pharmacopoeia and other related requirements, and meets 21CFR Part11. The product has passed the European CE certification.

主要技术参数 / Main technical parameters

洁净度等级 Cleanliness Level	泄漏率 Leakage Rate	无菌保证水平 Aseptic Assurance Level	噪声 Noise	照度 Intensity of Illumination	压差范围 Differential Pressure Range
A 级 A grade	0.5%	SAL ⩽ 10-6	⩽ 65dB	⩾ 500lux	0pa~+80Pa

灭菌柜出料隔离器 Autoclave Unloading Isolator

主要用途 / Main Application

灭菌柜出料隔离器用于对接灭菌柜，为已经灭菌后的无菌物品组装，提供无菌环境，防止微生物污染。

The autoclave unloading isolator is used for docking the autoclave to assemble sterilized articles and provide a sterile environment to prevent microbial contamination.

优势特点 / Main Characteristics and Advantages

- 设备腔体由 SUS316L 不锈钢制成，厚度为 3mm，可视窗采用 15mm 钢化玻璃制成；
- 系统符合人机工程学设计，洁净度为 ISO 4.8，提供全套 4Q 验证服务；
- 隔离器集成温湿度监测系统、压差监测系统、风速监测系统、过氧化氢浓度监测系统、粒子和浮游菌监测系统；
- 隔离器可在线检测泄漏率（压力衰减法），满足 ISO 10648，ISO14644，PDA TR34 的数据要求；
- 系统设计符合 GMP、ISO、ISPE、药典等相关要求，满足 21CFR Part11，产品通过欧盟 CE 认证；
- 根据工艺需求，可配置 RTP 阀。

+ The device chamber is made of SUS316L stainless steel with a thickness of 3mm. The visible window is made of 15mm toughened glass.
+ The system conforms to ergonomic design, the cleanliness is ISO 4.8, and a full set of 4Q verification service can be provided.
+ Integrated temperature and humidity monitoring system, pressure difference monitoring system, wind speed monitoring system, hydrogen peroxide concentration monitoring system, particle and plankton monitoring system;
+ The isolator can detect leakage rate online (pressure attenuation method), which meets the data requirements of ISO 10648, ISO14644 and PDA TR34.
+ The system design conforms to GMP, ISO, ISPE, pharmacopoeia and other related requirements, and meets 21CFR Part11. The product has passed the European CE certification.
+ RTP valves are available according to process requirements

主要技术参数 / Main Technical Parameters

洁净度等级 Cleanliness Level	泄漏率 Leakage Rate	无菌保证水平 Aseptic Assurance Level	噪声 Noise	照度 Intensity of Illumination	压差范围 Differential Pressure Range	裂隙风速 Crack Speed
A 级 A grade	0.5%	SAL ⩽ 10-6	⩽ 65dB	⩾ 500lux	0pa~+80Pa	⩾ 0.5m/s

无菌检查隔离器 Sterility Testing Isolator

主要用途 / Main Application

无菌检查隔离器为无菌检查试验提供无菌环境，可较好地防止微生物污染待测样品，避免试验用品和辅助设备的污染，提高无菌检查试验结果的准确性。

The sterility testing isolator provides a sterile environment for the sterility test, which can better prevent the microorganism from contaminating the sample to be tested, avoid the contamination of test supplies and auxiliary equipment, and improve the accuracy of the sterility test results.

优势特点 / Main Characteristics and Advantages

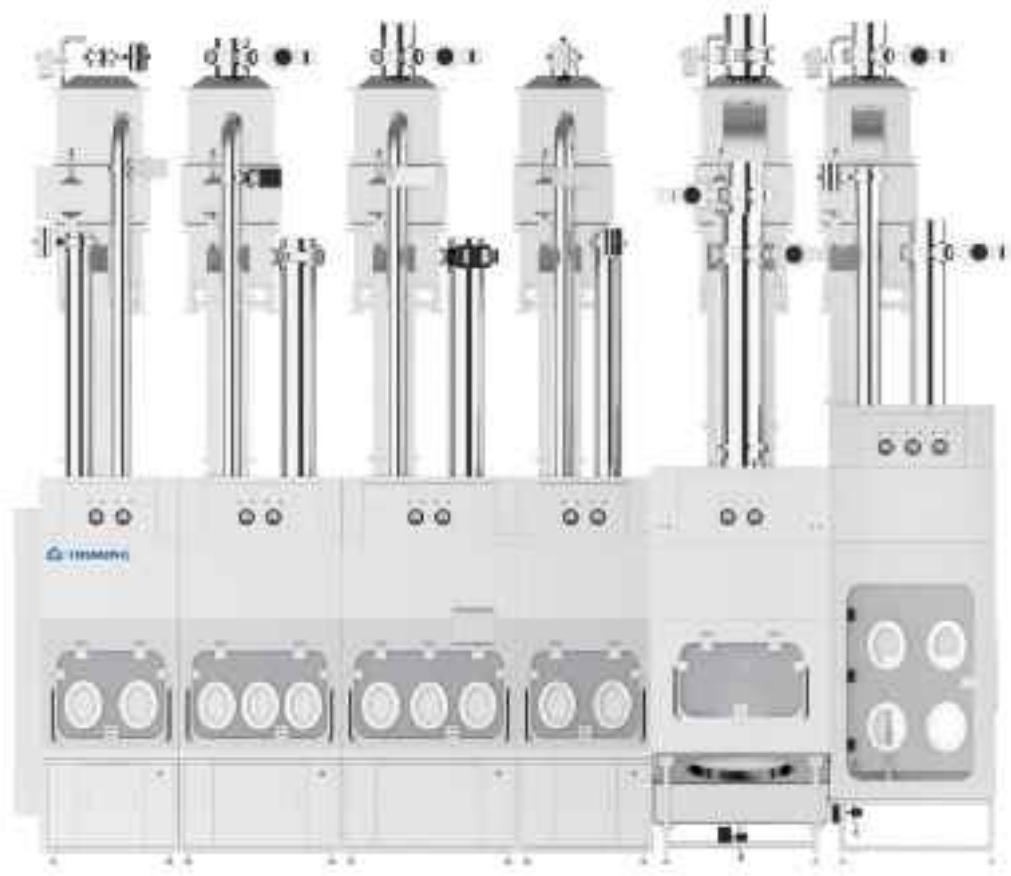
- 设备腔体由 SUS316L 不锈钢制成，厚度为 3mm，可视窗采用 15mm 钢化玻璃制成；
- 系统符合人机工程学设计，洁净度为 ISO 4.8，提供全套 4Q 验证服务；
- 隔离器集成温湿度监测系统、压差监测系统、风速监测系统、过氧化氢浓度监测系统、粒子和浮游菌监测系统；
- 隔离器可在线检测泄漏率（压力衰减法），满足 ISO 10648，ISO14644，PDA TR34 的数据要求；
- 系统设计符合 GMP、ISO、ISPE、药典等相关要求，满足 21CFR Part11，产品通过欧盟 CE 认证；
- 根据工艺需求，可配置无菌检查仪；
- 根据工艺需求，可配置 WIP 系统，可在线完成舱内清洗、管道喷淋及干燥；
- 根据工艺需求，可配置在线称重天平，数据可与系统集成或独立；
- 根据工艺需求，可配置 RTP 阀、垃圾桶、传递小车、置物架等。

- The device chamber is made of SUS316L stainless steel with a thickness of 3mm. The window can be made of 15mm toughened glass.
- The system conforms to ergonomic design, the cleanliness is ISO 4.8, and a full set of 4Q verification service is provided;
- Integrated temperature and humidity monitoring system, pressure difference monitoring system, wind speed monitoring system, hydrogen peroxide concentration monitoring system, particle and plankton monitoring system;
- The isolator can detect leakage rate online (pressure attenuation method), which meets the data requirements of ISO 10648, ISO14644 and PDA TR34.
- The system design conforms to GMP, ISO, ISPE, pharmacopoeia and other related requirements, and meets 21CFR Part11. The product has passed the European CE certification.
- According to the process requirements, can be equipped with sterility tester;
- According to the process requirements, WIP system can be configured to complete in-cabin cleaning, pipeline spraying and drying online;
- According to the process requirements, can be configured online weighing balance, data can be integrated with the system or independent;
- According to the process requirements, can be equipped with RTP valve, trash can, delivery cart, rack, etc.

主要技术参数 / Main Technical Parameters

洁净度等级 Cleanliness Level	泄漏率 Leakage Rate	无菌保证水平 Aseptic Assurance Level	噪声 Noise	照度 Intensity of Illumination	压差范围 Differential Pressure Range	裂隙风速 Crack Speed
A 级 A grade	0.5%	SAL ⩽ 10-6	⩽ 65dB	⩾ 500lux	0pa~+80Pa	⩾ 0.5m/s

原料药隔离器 API Isolator



主要用途 / Main Application

隔离系统为药品的无菌生产提供保障，并可防止毒性产品对生产人员的侵害。

The isolation system provides assurance for the aseptic production of drugs and prevents the production personnel from being harmed by toxic products.

优势特点 / Main Characteristics and Advantages

- 隔离系统为药品的无菌生产提供保障，并可防止毒性产品对生产人员的侵害；
- 设备腔体由 SUS316L 不锈钢制成，厚度为 3mm，可视窗采用 15mm 钢化玻璃制成；
- 系统符合人机工程学设计，洁净度为 ISO 4.8，提供全套 4Q 验证服务；
- 隔离器集成温湿度监测系统、压差监测系统、风速监测系统、过氧化氢浓度监测系统、手套光栅监测系统、粒子和浮游菌监测系统；
- 隔离器可在线检测泄漏率（压力衰减法），满足 ISO 10648，ISO14644，PDA TR34 的数据要求；
- 系统设计符合 GMP、ISO、ISPE、药典等相关要求，满足 21CFR Part11，产品通过欧盟 CE 认证；
- 根据工艺需求，可配置 WIP 系统，可在线完成舱内清洗、管道喷淋及干燥；
- 根据工艺需求，可配置 RTP 和 αβ 分离蝶阀；
- 根据工艺需求，可配置氮气系统及响应氧含量检测。
- 根据工艺需求，整机可满足防爆需求。

- The isolation system can guarantee the aseptic production of drugs and prevent the damage of toxic products to the production personnel.
- The device chamber is made of SUS316L stainless steel with a thickness of 3mm. The window can be made of 15mm toughened glass.
- The system conforms to ergonomic design, the cleanliness is ISO 4.8, and a full set of 4Q verification service is provided;
- Integrated temperature and humidity monitoring system, pressure difference monitoring system, wind speed monitoring system, hydrogen peroxide concentration monitoring system, glove grating monitoring system, particle and plankton monitoring system;
- The isolator can detect leakage rate online (pressure attenuation method), which meets the data requirements of ISO 10648, ISO14644 and PDA TR34.
- The system design conforms to GMP, ISO, ISPE, pharmacopoeia and other related requirements, and meets 21CFR Part11. The product has passed the European CE certification.
- According to the process requirements, WIP system can be configured to complete in-cabin cleaning, pipeline spraying and drying online;
- According to the process requirements, can be configured RTP and αβ separation butterfly valve;
- According to the process requirements, the nitrogen system and the response oxygen content can be configured.
- According to the process requirements, the whole machine can meet the anti-explosion requirements.

主要技术参数 / Main Technical Parameters

洁净度等级 Cleanliness Level	泄漏率 Leakage Rate	防护等级 Protection Grade	无菌保证水平 Aseptic Assurance Level	氧含量 Oxygen Content	噪声 Noise	照度 Intensity of Illumination	压差范围 Differential Pressure Range	裂隙风速 Crack Speed
A 级 A grade	0.5%	OEB 5	SAL ⩽ 10-6	⩽ 3%	⩽ 65dB	⩾ 500lux	-80pa~+80Pa	⩾ 0.5m/s

联动生产隔离系统 Combined Production Isolation System

主要用途 / Main Application

隔离系统为药品的无菌生产提供保障，并可防止毒性产品对生产人员的侵害。

The isolation system provides assurance for the aseptic production of drugs and prevents the production personnel from being harmed by toxic products.

优势特点 / Main Characteristics and Advantages

- 隔离系统为药品的无菌生产提供保障，并可防止毒性产品对生产人员的侵害；
- 隔离系统可配套水针、粉针、预充针和无菌粉末等生产线，A 级的单向气流，确保核心区域的产品，集成气化过氧化氢灭菌系统，达到 SAL ⩽ 10-6 的无菌保证水平；
- 设备腔体由 SUS316L 不锈钢制成，厚度为 3mm，可视窗采用 15mm 钢化玻璃制成；
- 系统符合人机工程学设计，洁净度为 ISO 4.8，提供全套 4Q 验证服务；
- 隔离器集成温湿度监测系统、压差监测系统、风速监测系统、过氧化氢浓度监测系统、手套光栅监测系统、粒子和浮游菌监测系统；
- 隔离器可在线检测泄漏率（压力衰减法），满足 ISO 10648，ISO14644，PDA TR34 的数据要求；
- 系统设计符合 GMP、ISO、ISPE、药典等相关要求，满足 21CFR Part11，产品通过欧盟 CE 认证；
- 根据工艺需求，可配置 WIP 系统，可在线完成舱内清洗、管道喷淋及干燥；
- 根据工艺需求，可配置 RTP 阀；
- 根据工艺需求，可配置立式胶塞清洗机，便于工业化生产的胶塞无菌转运。

- The isolation system can guarantee the aseptic production of drugs and prevent the damage of toxic products to the production personnel.
- The isolation system can be equipped with production lines such as water needle, powder needle, pre-filled needle and sterile powder, with one-way A-level airflow to ensure the products in the core area, and integrate the vaporized hydrogen peroxide sterilization system to reach the sterile guarantee level of SAL ⩽ 10-6.
- The device chamber is made of SUS316L stainless steel with a thickness of 3mm. The visible window is made of 15mm toughened glass.
- The system conforms to ergonomic design, the cleanliness is ISO 4.8, and a full set of 4Q verification service is provided;
- Integrated temperature and humidity monitoring system, pressure difference monitoring system, wind speed monitoring system, hydrogen peroxide concentration monitoring system, glove grating monitoring system, particle and plankton monitoring system;
- The isolator can detect leakage rate online (pressure attenuation method), which meets the data requirements of ISO 10648, ISO14644 and PDA TR34.
- The system design conforms to GMP, ISO, ISPE, pharmacopoeia and other related requirements, and meets 21CFR Part11. The product has passed the European CE certification.
- According to the process requirements, WIP system can be configured to complete in-cabin cleaning, pipeline spraying and drying online;
- According to the process requirements, can be configured with RTP valve;
- According to the process requirements, it can be equipped with vertical rubber plug cleaning machine, which is easy for sterile transport of industrial produced rubber plug.

主要技术参数 / Main Technical Parameterss

洁净度等级 Cleanliness Level	泄漏率 Eakage Rate	无菌保证水平 Aseptic Assurance Level	噪声 Noise	照度 Intensity of Illumination	压差范围 Differential Pressure Range	裂隙风速 Crack Speed
A 级 A grade	1%	SAL ⩽ 10-6	⩽ 65dB	⩾ 500lux	-80pa~+80Pa	⩾ 0.5m/s

服务理念

400-9988-900

秉承“一切为客户着想，为一切客户着想，为客户着想一切”的理念，以“为客户创造价值”为己任，楚天专注于打造一流的研发、设计、销售、制造、服务团队及服务管理体系，为客户提供高效、优质的产品与服务。

◎ 项目规划支持

楚天拥有系列专业医药设计院、产品研究院，一批行业资深科研技术人员，无菌制药工艺的验证专家、教授等，为客户的项目提供科学、有效的技术规划支持。

◎ 过程保障服务

楚天推出的医药装备整体解决方案，实现药品生产过程的全自动化、无菌化，智能检测、分选，以及计算机验证保障，生产出让市场“放心”的产品。

◎ 走进园区服务

楚天作为设备供应商，不仅仅将行业法规标准融入到产品设计、制造中，还让法规标准以讲座、交流的形式走进园区，与药企的工艺、生产形成互动与融合。

◎ 设备管理咨询服务

楚天致力于满足客户效益最大化需求，提供一揽子的设备管理模式，协同药厂实现投入最小化，产出最大化。

◎ 坚持“以客户为中心”， 以匠人之心打造极致服务体验，为客户创造更多价值

34 全国 34 个省（市）

365 全年 365 天

7x24 7X24 小时服务时间

◎ 我们随时待命为客户单位设备正常运行保驾护航

+ 现场安装、调试、验收
+ 设备工艺、操作、维护等相关培训
+ 周期性的定期上门维护与回访
+ 设备各部件性能的检测与保养
+ 备品备件的及时供应
+ 产品技术升级与技术二次开发
+ 设备大修

Service Concept

400-9988-900

Adhering to concept of “all for customers, for all customers”, and with the mission of “creating value for customers”, TRUKING focuses on building first-class R&D, design, sales, manufacturing, service teams and service management system to offer high-efficient and high-quality products and services for the customers.

◎ Project Planning Support

TRUKING has a series of professional medical and pharmaceutical design institutes, product research institutes, a group of senior scientific research and technical personnel, aseptic pharmaceutical process verification experts, professors, etc., to provide scientific and effective technical planning support for customers' projects.

◎ Process Assurance Service

TRUKING launched the overall solution for medical & pharmaceutical equipment realizing the full automation and aseptic production process, intelligent detection and sorting of the drug, as well as computer verification assurance so as to produce assured products for market.

◎ Service In The Park

As an equipment supplier, TRUKING not only integrates industrial regulations and standards into product design and manufacturing, but also introduces the industrial regulations and standards into Truking industrial park in the form of lectures and exchanges to interact and integrate with the technology and production of pharmaceutical enterprises.

◎ Equipment Management Consultation Service

TRUKING aims to satisfy the maximum benefited demands of the customer and to provide a package of equipment management services to realize minimization investment and maximization production output together with pharmaceutical factories.

◎ Adhere to the philosophy of "customer-centric", TRUKING creates the extraordinary service experience with the spirit of the craftsman, to create more value for customers.

◎ We are always ready to escort the normal operation of the customer's equipment.

+ Onsite equipment installation, commissioning, acceptance
+ Training for equipment process, operation and maintenance
+ Periodic door-to-door maintenance and return visit
+ Performance test and maintenance for machinery parts
+ Timely supply of spare parts
+ Product technology upgrading and secondary development
+ Equipment overhaul

www.truking.com

TRUKING

地址 Add：国家级宁乡经济技术开发区楚天科技工业园　邮编 P.C：410600
Truking Technology Industrial Park, Ningxiang National Economic and Technological Development Zone
电话 Tel：0731-87938288　传真 Fax：0731-87938201
邮箱 E-mai：truking@truking.cn