

### www.truking.com



### 楚天华通医药设备有限公司

TRUKING WATERTOWN PHARMACEUTICAL EQUIPMENT CO.,LTD.

地址 Add: 吉林省长春九台经济开发区华通大街 888 号

No.888 Watertown Avenue, Jiutai Economic Development Area, Changchun, Jilin Province. 销售服务 Sales Service: 0431-81989116 客户服务 Customer Service: 0431-81989135

传真 Fax No: 0431-81989076 邮编 Post Code: 130500

产品技术改进恕不另行通知,本公司保留对本手册内容的最终解释权,本册图片供参考,以实物为准。 2023 年 05 月版

The company reserves the right to interpret the contents of this manual without prior notice. The pictures in this manual are for reference and subject to the actual conditions.

May 2023 Edition





### 楚天华通医药设备有限公司

TRUKING WATERTOWN PHARMACEUTICAL EQUIPMENT CO.,LTD.

# 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



#### 公司简介 -01-

Company profile

# **洁净型双管板换热器** -02-Clean Double Tube Sheet Heat Exchanger

### 毛细管换热器 -08-

Capillary Heat Exchanger

### 质量控制 -11-

**Quality Control** 

# **质量文件** -12-Quality Documents

### 售后服务 -12-

After-sales Service



#### **TRUKING**

#### 公司简介 Company profile





楚天华通医药设备有限公司系楚天科技股份有限公司全资子公司,始建于1993年,是目前亚洲领军制药用水系统(制备、储存和分配)、配液系统、不锈钢压力容器、污水处理、蒸发浓缩结晶、换热器研发制造基地,装备及制造工艺处于行业优级水平,员工总数1300余人,资产总额20亿元,服务于全球1000余家制药企业。

公司位于长春九台经济开发区,是中国制药装备行业协会理事单位,中国医药设备工程协会、中国膜工业协会会员单位,获评定为国家级高新技术企业、吉林省专精特新企业、吉林省级企业技术中心,获得省级创新型科技企业、长春市百强民营企业、长春市科技型小巨人企业等荣誉。公司拥有中国特种设备压力容器D级(10MPa以下的一类、二类、三类压力容器)设计与制造资质、压力管道(GC2)安装许可证、建筑机电安装工程专业承包贰级资质、环保工程专业承包贰级、环境工程设计专项(水污染防治工程)乙级、美国ASME(U)钢印设计与制造资质、欧盟CE(PED、MD)认证资质。截至2023年4月,公司共提出中国专利申请320项,有效专利180项,另提出1件PCT国际专利申请。产品已出口美国、意大利、比利时、希腊、土耳其、俄罗斯、韩国、泰国、越南、印尼、印度、埃及、沙特、摩洛哥、秘鲁等30多个国家和地区,国际市场占有率正逐年快速提升。

公司拥有经验丰富的研发技术团队,覆盖工程设计、项目管理、测试调试、验证与咨询服务,联合楚天科技、德国ROMACO集团、四川省医药设计院共同承接制药企业EPCM总包服务,为制药企业提供工程工艺优化、产品的全生命周期管理与服务。

2021年公司确认新建楚天华通医药装备智能制造产业园项目,位于长春市九台经济技术开发区中古医药产业园。项目新购地36.1117万平方米,计划在5年内分三期完成项目整体建设任务,项目建成后,将崛起楚天华通研发中心大楼、智能车间、员工公寓以及商务接待中心等现代化智能配套公用工程。一期工程建筑面积6万平米,预计2023年7月投产。作为楚天华通年产5000台套医药装备的智能制造基地,楚天华通医药装备智能制造产业园项目完成后将大幅提升企业产能,将进一步推动企业战略目标的实现。

公司坚持"做受尊敬的人、造受尊敬的产品、办受尊敬的企业"的核心价值观,秉承"要么唯一,要么第一"的理念,弘扬"因为执着,所以卓越"的精神,将楚天华通打造成全球制药用水系统领军企业之一。

Truking Watertown Pharmaceutical Equipment Co., LTD., a wholly-owned subsidiary of Truking Technology Limited, was founded in 1993. It is the leading R&D and manufacturing base of pharmaceutical water system (preparation, storage and distribution), liquid preparation system, stainless steel pressure vessel, sewage treatment, evaporation, crystallization and heat exchanger in Asia. With more than 1300 employees and 2 billion yuan of assets, the company serves more than 1000 pharmaceutical enterprises around the world.

Truking Watertown is located in Jiutai Economic Development Zone, Changchun. It is a member of China Pharmaceutical Equipment Industry Association, China Pharmaceutical Equipment Engineering Association and China Membrane Industry Association. It has been rated as a national high-tech enterprise, Provincial Specialized and Sophisticated Enterprise, Provincial Enterprise Technology Center. It has been honored as provincial innovative technology Enterprise, Changchun Top 100 Private Enterprise, and Changchun Small Giant Technology Enterprise. Truking Watertown has Chinese special equipment Class D (Class I, Class II and Class III below 10MPa) pressure vessel design and manufacturing license, Pressure pipeline (GC2) installation license, construction mechanical and electrical installation engineering contracting Class II, environmental engineering design special (water pollution control engineering) Class B, ASME(U) steel seal design and design manufacturing qualification, EU CE(PED, MD) certification qualification. Truking Watertown has applied for 320 patents, 180 patents of which have been authorized until April 2023, and one PCT international patent application. Products have been exported to the United States, Italy, Belgium, Greece, Turkey, Russia, South Korea, Thailand, Vietnam, Indonesia, India, Egypt, Saudi Arabia, Morocco, Peru and other 30 countries and regions, the international market share is rapidly increasing year by year.

Truking Watertown has an experienced R&D technical team, covering engineering design, project management, testing and commissioning, validation and consulting services. Together with Truking Technology, Germany ROMACO Group and Sichuan Pharmaceutical Design Institute, the company jointly undertakes EPCM general contract services for pharmaceutical enterprises, providing engineering process optimization and product lifecycle management and services for pharmaceutical enterprises.

In 2021, Truking Watertown pharmaceutical equipment Intelligent Manufacturing Industrial Park project started, located in Jiutai Economic and Technological Development Zone of Changchun Medicine Industrial Park. The new plant occupies 361,117 square meters. It is planned to complete the overall construction in three phases within 5 years. After the completion of the construction, Truking Watertown R&D Center building, intelligent workshop, employee apartment and business reception center and other modern intelligent supporting utilities will be used. The first phase of the project covers a construction area of 60,000 square meters and is expected to be put into operation in July 2023. As base of Truking Watertown with an annual output of 5,000 sets, pharmaceutical equipment intelligent manufacturing Industrial Park will greatly improve the enterprise's production capacity after the completion of the project, which will further promote the realization of the strategic objectives of the enterprise.

We insist on the core value of being respected person, making respected product and running respected enterprise and adhere to the philosophy to be the unique or to be the first and promote the spirit of Because of persistence, we are superexcellent to make Truking Watertown be one of the leading pharmaceutical water system enterprises all over the world.

01 TRUKING

# 洁净型双管板换热器 Clean Double Tube Sheet Heat Exchanger



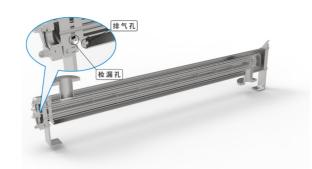
#### 性能特点 / Characteristics



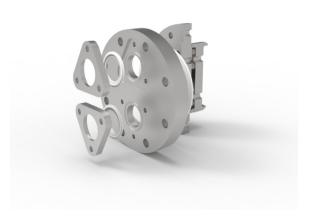


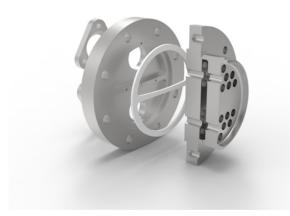
- ◎ 设计压力:管程 9bar,壳程 9bar,满足多种工况压力需求,高压工况设置蒸汽防冲板,减少换热管震动。
- ◎ 洁净连接: 换热器管程入口采用卫生型压盖连接座或卫生型卡盘连接形式,无物理结构死角,便于安装, 入口自带倾角,保证自排净。
- ◎ 洁净保温:换热器整体采用不锈钢保温形式,设计美观,依据洁净等级要求,换热器可采用整体密闭保温 形式,无缝隙及死角,整体密闭保温壳体设置排气口,便于壳程侧压力测试及保温侧热膨胀压力释放,维 持压力平衡。
- ◎ 高效传热: 优选无缝 φ10 换热管,根据流量制定换热管排布,相同换热工况下传热效率更高。
- Design pressure: pipe side 9bar, shell side 9bar, meet the pressure requirement of various working conditions, high pressure working conditions set steam anti-impact sheet, reduce the vibration of the heat exchange tube.
- Clean connection: the inlet of the pipe side of the heat exchanger adopts the sanitary gland connection seat or sanitary clamp connection, no dead leg of physical structure, easy to install. The inlet has its own inclination angle to ensure selfdrainage.
- Clean heat preservation: the whole heat exchanger adopts the stainless-steel heat preservation, the design is beautiful, according to the clean grade requirements, the heat exchanger can use the whole closed heat preservation, no gap and dead leg, the whole closed heat preservation shell is set the exhaust port, easy to shell side pressure test and heat preservation side thermal expansion pressure release, maintain the pressure balance.
- Efficient heat transfer: seamless φ10 heat exchange tube is preferred, and the heat exchange tube arrangement is made according to the flow rate. The heat transfer efficiency is higher under the same heat exchange condition.





- ◎ 高效安装: 支座自带安装倾角,便于设备自排净,同时壳程对外接口水平安装,易于对外公用工程连接, 换热器支座安装方位可根据实际工况调整,适合不同方位安装需求。
- ◎ 正确选用: U型管换热器应用于冷却工况,可更好地吸收因温度变化引起的应力,降低设备运行风险; L型换热器更适合流量较大的分配系统热消毒。
- Efficient installation: the bearing has its own installation angle, easy to self-discharge, shell side external interface horizontal installation, easy to connect utilities, heat exchanger bearing installation direction can be adjusted according to the actual working condition, suitable for different installation needs.
- Correct selection: U-tube heat exchanger applied to cooling conditions, can better absorb the stress caused by temperature changes, reduce the risk of equipment operation; L type heat exchanger is more suitable for heat sanitization of distribution system with large flow rate.





- ◎ 管板设计 Tube sheet design:
  - ·· 整体式双管板结构设计,降低换热管与管板之间的切向应力。
  - · · 换热器设置检漏孔,确保双管板换热器泄漏时及时发现。
  - ··· 换热管与内外管板采用无缝管双强度胀接形式,降低焊接导致热影响区焊接应力导致焊口泄漏风险。
- Integral double tube-sheet structure design, reduce the tangential stress between heat exchange tube and tube-sheet.
- The heat exchanger is equipped with leak detection holes to ensure that the leakage of the double-tube-sheet heat exchanger is found in time.
- The heat exchange tube and internal and external tube sheet adopt seamless tube double strength expansion, reduce welding stress caused by heat affected zone welding leakage risk.





#### ◎ 封头设计 Head design:

- ·· U型管换热器封头分程隔板采用轴向及径向双向倾角设计,保证停机残留水从排空口排净,实现零残留。
- … 进出口过流边界与封头法兰腔体上下轮廓相切,确保洁净侧无间隙及死水重合。
- The head partition of U-tube heat exchanger adopts axial and radial bidirectional dip design to ensure that the residual water can be discharged from the exhaust port and zero residue.
- The inlet and outlet flow boundary is tangent to the upper and lower contour of the head flange chamber to ensure that there is no clearance and water overlap on the clean side.
- ◎ 密封设计 Seal design:
  - · · 密封垫片采用自定位、自密封形式,便于维护、提高安装精度。
  - · · 密封垫片内轮廓与法兰腔体内轮廓重合,无物理结构死角。
- Sealing gasket adopts self-positioning and self-sealing, which is easy to maintain and improve installation accuracy.
- Sealing gasket inner contour coincides with flange chamber inner contour, and there is no dead leg of physical structure.
- ◎ 优选材质 Preferred material:
  - · · 换热管采用 S31603 及以上材质无缝管。
  - ·· 密封垫采用 PTFE 材质,符合 FDA 要求。
  - · · 保温材料采用优质高阻热、无脱落、无可溶性析出的硅酸铝材料。
- Seamless tube made of S31603 or better material.
- The sealing gasket is made of PTFE, meet FDA requirement.
- Thermal insulation material is made of high-quality aluminum silicate material with high heat resistance, no shedding and no soluble precipitation.





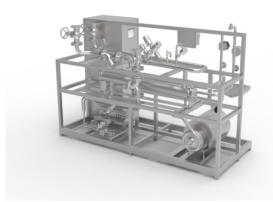
- ◎ 表面处理:选用洁净换热管,可进行内外表面的整体电解抛光处理,满足特殊洁净工况要求  $RA \le 0.4 \mu m$ ,设备外表面粗糙度可达到  $RA \le 0.8$ ,可整体进行电解抛光处理,满足环境对于设备外表的洁净要求。
- Surface finish: the clean heat exchange tube can be used for the overall electrolytic polishing of the internal and external surfaces, which meets the requirements of special cleaning conditions RA  $\leq 0.4 \mu m$ . The surface roughness of the external surface of the equipment can reach RA  $\leq 0.8 \mu m$ . The overall electrolytic polishing can meet the environmental requirements for the surface of the equipment.

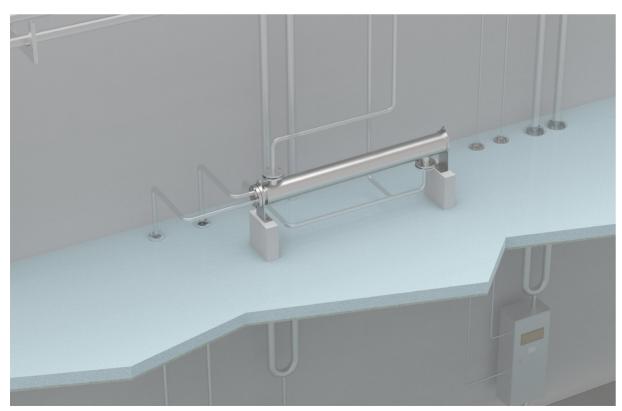
03 TRUKING

# 

- ◎ 注射用水冷点降温工况;
- ◎ 配液系统,CIP 循环清洗系统升温;
- ◎ 分配循环系统巴氏消毒或者过热水灭菌等;
- ◎ 系统余热回收利用,高温热排降温等工况;
- ◎ 冷热介质交叉换热、大流量换热等特殊设计 的串并联工况;
- WFI cold point of use cooling condition;
- Liquid distribution system, CIP cycle cleaning system heating up;
- Distribution circulation system pasteurization or sterilization of superhot water;
- System waste heat recovery and utilization, high temperature heat discharge cooling conditions;
- Cold and hot medium heat exchange, large flow heat exchange and other specially designed series and parallel working conditions;



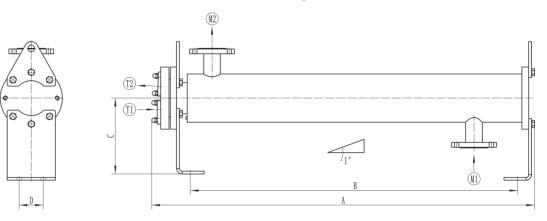




# ● 设备型号 / Equipment Model

#### U 型管换热器部分型号

U-tube Heat Exchanger Model



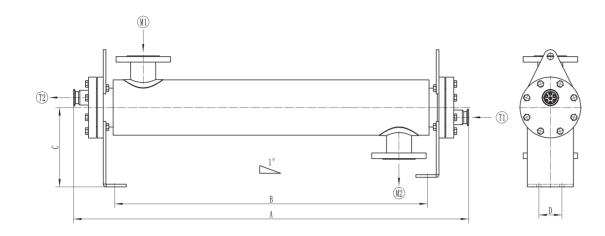
——P 系列 / P series

换热器型号 Model	换热面积 Area (m²)	筒体直径 Column diameter (mm)	T1、T2 尺寸 Size	M1、M2 尺寸 Size	A (mm)	B (mm)	C (mm)	D (mm)
HE0.4-P-U089	0.4	089	1"	DN40	1610	1450	220	70
HE0.6-P-U089	0.6	089	1"	DN40	2110	1950	220	70
HE0.8-P-U089	0.8	089	1"	DN40	2610	2450	220	70
HE0.5-P-U101	0.5	101	1.5"	DN40	1110	950	245	70
HE0.8-P-U101	0.8	101	1.5"	DN50	1610	1450	245	70
HE1.1-P-U101	1.1	101	1.5"	DN50	2110	1950	245	70
HE1.4-P-U101	1.4	101	1.5"	DN50	2610	2450	245	70
HE0.7-P-U114	0.7	114	1.5"	DN65	1110	950	245	70
HE1.1-P-U114	1.1	114	1.5"	DN65	1610	1450	245	70
HE1.5-P-U114	1.5	114	1.5"	DN65	2110	1950	245	70
HE1.9-P-U114	1.9	114	1.5"	DN65	2610	2450	245	70
HE1.1-P-U140	1.1	140	2"	DN80	1110	950	245	80
HE1.7-P-U140	1.7	140	2"	DN80	1610	1450	245	80
HE2.3-P-U140	2.3	140	2"	DN80	2110	1950	245	80
HE1.8-P-U168	1.8	168	2"	DN100	1110	950	245	90
HE2.8-P-U168	2.8	168	2"	DN100	1610	1450	245	90
HE3.8-P-U168	3.8	168	2"	DN100	2110	1950	245	90

洁净型双管板换热器 / Clean Double Tube Sheet Heat Exchanger / 毛细管换热器

#### L型列管换热器部分型号

L-type Heat Exchanger Model



——P 系列 / P series

换热器型号 Model	换热面积 Area (m²)	筒体直径 Column diameter (mm)	T1、T2 尺寸 Size	M1、M2 尺寸 Size	A (mm)	B (mm)	C (mm)	D (mm)
HE0.6-P-L089	0.6	089	1"	DN40	1210	950	220	70
HE0.9-P-L089	0.9	089	1"	DN40	1710	1450	220	70
HE1.2-P-L089	1.2	089	1"	DN40	2210	1950	220	70
HE1.5-P-L089	1.5	089	1"	DN40	2710	2450	220	70
HE0.8-P-L101	0.8	101	1.5"	DN50	1210	950	245	70
HE1.2-P-L101	1.2	101	1.5"	DN50	1710	1450	245	70
HE1.6-P-L101	1.6	101	1.5"	DN50	2210	1950	245	70
HE2.0-P-L101	2.0	101	1.5"	DN50	2710	2450	245	70
HE1.1-P-L114	1.1	114	1.5"	DN65	1210	950	245	70
HE1.7-P-L114	1.7	114	1.5"	DN65	1710	1450	245	70
HE2.3-P-L114	2.3	114	1.5"	DN65	2210	1950	245	70
HE2.9-P-L114	2.9	114	1.5"	DN65	2710	2450	245	70
HE1.9-P-L140	1.9	140	2"	DN80	1210	950	245	80
HE2.8-P-L140	2.8	140	2"	DN80	1710	1450	245	80
HE3.8-P-L140	3.8	140	2"	DN80	2210	1950	245	80
HE4.7-P-L140	4.7	140	2"	DN80	2710	2450	245	80

# 毛细管换热器 Capillary Heat Exchanger



### 性能特点 / Characteristics



- ◎ 双管板结构设置,避免管壳程的交叉污染。
- ◎ 设计压力为管程 9bar,壳程 9bar,满足不同工况压力需求。
- ◎ 体积小,管程、壳程均采用标准卫生型卡盘连接,安装方便,便于拆卸。
- ◎ 换热器整机 316L 材质,无其他非卫生级材料,可直接应用在高等级洁净区域。
- ◎ 换热器整体一次性烧结成型,无焊接等热影响区,不变形,可有效去除加工应力。
- ◎ 换热管细,管壁薄,换热均匀,传热系数高,单位面积上可提供更大的热负荷。
- Double tube sheet structure to avoid cross contamination of shell and tube sides.
- The measured pressure is 9bar pipe side and 9bar shell side, which can meet the pressure requirements of different working conditions.
- Small size, pipe and shell sides are connected by standard sanitary clamp, easy to install, easy to disassemble.
- Heat exchanger machine 316L material, no other non-sanitary materials, can be directly used in high grade clean area.
- Heat exchanger whole one-time sintering molding, no welding and other heat affected area, no deformation, can effectively remove processing stress.
- Thin heat transfer tube, thin wall, uniform heat transfer, high heat transfer coefficient, per unit area can provide greater heat load.

毛细管换热器 / Capillary Heat Exchanger Capillary Heat Exchanger / 毛细管换热器

### TRUKING

### 应用领域 / Application Field

#### ·洁净冷点降温 Clean Cold Point of Use Cooling



可应用于一体式冷点降温模块,设计满足高等级洁净场合需求,安装方便,尤其适用于冷点增加或者后期改造,节约现场施工时间。

It can be applied to the integrated cold point cooling module, designed to
meet the needs of high-level clean occasions, easy installation, especially
suitable for the increase of cold point or later transformation, saving the site
construction time.

#### ·纯蒸汽取样 Pure Steam Sampling



纯蒸汽的品质影响着后端工序产品的质量安全,洁净型毛细管换热器可应用在纯蒸汽制备系统作为在线 实时取样检测装置,也可应用在纯蒸汽分配使用点取样作为离线取样检测装置。

- The quality of pure steam affects the quality and safety of the products in the back-end process. The clean capillary heat exchanger can be used in the pure steam preparation system as an online real-time sampling detection device, and can also be used in the pure steam distribution point of use sampling as an off-line sampling detection device.



## 设备型号 / Equipment Model

#### 洁净毛细管换热器型号

Clean Capillary Heat Exchanger Model

换热器型号 Model	面积 Area (m²)	系列代号 Series	结构形式 Constructure	筒体直径 Column diameter (mm)	换热器长度 Length (mm)
HE0.05-P-C25.4	0.05	Р	С	25.4	254
HE0.07-P-C25.4	0.07	Р	С	25.4	381
HE0.09-P-C25.4	0.09	Р	С	25.4	508
HE0.26-P-C38.1	0.26	Р	С	38.1	508
HE0.33-P-C38.1	0.33	Р	С	38.1	635
HE0.39-P-C38.1	0.39	Р	С	38.1	762
HE0.53-P-C38.1	0.53	Р	С	38.1	1016
HE0.44-P-C50.8	0.44	Р	С	50.8	508
HE0.54-P-C50.8	0.54	Р	С	50.8	635
HE0.65-P-C50.8	0.65	Р	С	50.8	762
HE0.87-P-C50.8	0.87	Р	С	50.8	1016
HE0.78-P-C63.5	0.78	Р	С	63.5	508
HE0.98-P-C63.5	0.98	Р	С	63.5	635
HE1.17-P-C63.5	1.17	Р	С	63.5	762
HE1.56-P-C63.5	1.56	Р	С	63.5	1016
HE1.21-P-C76.2	1.21	Р	С	76.2	508
HE1.51-P-C76.2	1.51	Р	С	76.2	635
HE1.82-P-C76.2	1.82	Р	С	76.2	762
HE2.42-P-C76.2	2.42	Р	С	76.2	1016
HE2.52-P-C101.6	2.52	Р	С	101.6	635
HE3.02-P-C101.6	3.02	Р	С	101.6	762
HE4.03-P-C101.6	4.03	Р	С	101.6	1016

质量控制 / Quality Control Quality Documents / 质量文件 After-sales Service / 售后服务

# 质量控制 Quality Control

#### ·表面处理 Surface Finish

表面粗糙度属于微观几何形状误差,表面粗糙度越小,则表面越光滑,楚天华通拥有国内行业最大的厂内不锈钢电解车间,电解抛光可有效去除不锈钢表面加工毛刺及游离铁离子,降低表面粗糙度,降低结垢及红锈滋生风险,延长设备使用寿命。

 Micro geometric surface roughness shape error, the smaller the roughness, the smoother the surface, Truking Watertown has domestic industry's largest factory of stainless-steel electrolytic workshop, electrolytic polishing can effectively remove the stainless-steel surface machining burrs and free iron ions, reduce the surface roughness, reduce the risk of scaling and red rust breeding, prolong the service life of equipment.



#### ·加工制造 Processing and Manufacturing

设备齐全的机加工车间,换热器所有机加件均为华通自行加工制造,过程质量及过程文件可控、可追溯。

- The well-equipped machining workshop, all heat exchanger parts are manufactured by Watertown, process quality and process documents controllable, traceable.





## 质量文件 Quality Documents

提供标准符合 GMP 要求的过程文件、验证文件,有效保证产品验证文件真实、可追溯、合规性。

- Provide process documents and validation documents that meet GMP requirements to effectively ensure the authenticity, tracea bility and compliance of product validation documents.
- ◎ 提供换热器部件图;

- Provide heat exchanger parts drawings;

◎ 换热器强度计算书;

- Heat exchanger strength calculation;
- ◎ 换热器安装操作维护手册
- Heat exchanger installation, operation and maintenance manual;

◎ 使用材料的材质证明;

- Material certificate of materials used;

- Process quality system documents;

◎ 过程质量体系文件;

- Pickling passivation report and roughness certificate;
- ◎ 酸洗钝化报告及粗糙度证明;
- Compliance certification of flow parts and sealing materials;
- ◎ 过流部件及密封材质合规性证明;◎ 焊工资质、焊接工艺流程、焊缝图;
- Welder qualification, welding process, weld drawing;

## 售后服务 After-sales Service

选择了楚天华通就等于选择了以下优先权:

- Choosing Truking Watertown means choosing the following priorities:
- ◎ 高效的交货周期,相同产品储备充足;
- ◎ 高质量的产品及符合法规要求的验证体系文件;
- ◎ 源于对产品的自信及口碑,提供两年质量保障;
- ◎ 免费提供两年的易损备件,保证产品生命周期稳定运行;
- ◎ 拥有全国七大区域服务中心,全天候24小时的尊享服务;
- Efficient delivery cycle, sufficient stock of the same products;
- High quality products and validation system documents compliance with regulatory requirements;
- From the confidence and reputation of the product, to provide two years' warranty;
- Free provision of two years of vulnerable spare parts, to ensure stable operation of product life cycle;
- With seven national regional service centers, 24 hours a day service;