

# STERILIZATION QUALIFICATION

华福按照ENISO13485:2016,ENISO11135:2014标准的要求建立了质量管理体系。通过了南德TUV公司的ENISO13485:2016,ENISO11135:2014认证。



## STERILIZATION SERVICE

# 灭菌服务

公司设备齐全，配置了强制升温，调湿的预处理室，符合CE的灭菌罐和强制升温换气的解析室，配备了灭菌确认用的无线温湿度传感器，配置了微生物实验室用于测产品初始污染菌和无菌，配置了和气象色谱仪用于残留EO/ECH分析。  
公司技术人员从事灭菌管理和灭菌确认工作多年，有能力协助客户完成第三方或第三方的审核。

### 企业微介绍

浙江华福医用器材有限公司致力于为医疗产业提供专业的技术服务，坐落在嘉兴市平湖市新兴一路688号，是长三角的中心地带，交通极为便利。

### 服务项目：灭菌技术服务

为客户的产品设计最高效、最可靠的灭菌工艺，让客户用最低的成本，得到高价值的服务回报。制定灭菌确认方案，按照ISO11135:2014要求进行灭菌确认和再确认。

### 服务项目：日常灭菌服务

可以按照客户要求的参数或者经过灭菌验证的参数，为客户的产品进行日常环氧乙烷消毒/灭菌服务，并提供相关的灭菌参数记录、过程监控记录、检测报告等便于客户日常追溯。



## STERILIZATION QUALIFICATION

The company has established a quality management system in accordance with the requirements of eniso13485:2016 and eniso11135:2014. It has passed the certification of eniso13485:2016 and eniso11135:2014 of TUV company of South Germany.



## STERILIZATION SERVICE

The company has complete equipment, equipped with pre-treatment room for forced temperature rise and humidity control, sterilization tank conforming to CE and analysis room for forced heating and air exchange, wireless temperature and humidity sensor for sterilization confirmation, microorganism laboratory for detecting initial contamination bacteria and sterility of products, and meteorological chromatograph for residual EO / ECH analysis.

### Company Introduction

Zhejiang Huafu Medical Equipment Co., Ltd. is committed to providing professional technical services for the medical industry. Located at No. 688, Xinxing 1st Road, Pinghu City, Jiaxing City, Zhejiang Huafu Medical Equipment Co., Ltd. is the center of the Yangtze River Delta, with convenient transportation.

### Service items: Sterilization technical service

Design the most efficient and reliable sterilization process for customers' products, so that customers can get high value service return with the lowest cost. Develop sterilization confirmation scheme, and carry out sterilization confirmation and re confirmation according to iso11135:2014.

### Service items: Daily sterilization service

It can provide daily ethylene oxide disinfection / sterilization services for customers' products according to the parameters required by customers or verified by sterilization, and provide relevant sterilization parameter records, process monitoring records, test reports, etc., so as to facilitate customers' daily traceability.

