Demonstration project for conversion from HCFC-141b-based technology to iso-paraffin and siloxane (KC-6) technology for cleaning in the manufacture of medical devices at Zhejiang Kindly Medical Devices Co. Ltd.

FINAL REPORT

August 2014

Submitted by:

Foreign Economic Cooperation Office, Ministry of Environmental Protection, China (FECO/MEP)

and

United Nations Development Programme (UNDP)

Executive Summary

Demonstration project for conversion from HCFC-141b-based technology to iso-paraffin and siloxane (KC-6) technology for cleaning in the manufacture of medical devices at Zhejiang Kindly Medical Devices Co. Ltd. (KDL) was approved by the 64th Executive Committee meeting at a funding level of US$557,667 from the Multilateral Fund and $205,616 as bilateral cooperation from the Government of Japan.

This demonstration project was successfully implemented, and established the suitability of KC-6 technology as a viable replacement for HCFC-141b as solvent and Silicone oil diluent in the manufacture of needles at Zhejiang Kindly Medical Devices Co. Ltd.

The project activities includes product redesign and development, equipment installation and modifications safety and other measures to handle the flammability, laboratory testing and performance evaluation, product trials, biocompatibility and drug-compatibility testing, production line conversion, technical assistance and training.

The successful completion of the demonstration project contributes towards promotion of this technology for medical devices production and enables cost-effective conversions at other similar manufacturers in this sub-sector.

1. Introduction

In 2007, the 19th Meeting of Parties of the Montreal Protocol agreed on accelerated phase-out of HCFCs. To achieve the compliance goal, China is implementing HCFCs phase-out sector plans in the solvent sector from 2012. The KDL project was established as a demonstration earlier in 2010 for preparation and support of the sector plan implementation.

The Executive Committee approved the KDL demonstration project at the 64th meeting in 2011 at a funding level of US $ 557,667. The project's implementing agency is UNDP. Total approved funding from MLF was US $ 352,051. Additional funding of US$ 205,616 has been approved as a bilateral cooperation component with the Government of Japan, with UNDP as the implementing agency. The national agency implementing this project is Foreign Economic Cooperation Office (FECO), Ministry Of Environmental Protection, China.

The objective of this demonstration project is to establish the suitability of KC-6 technology as a viable replacement for HCFC-141b as a solvent in the manufacture of needles at Zhejiang KDL Co. Ltd.

As a result of the conversion project, about 27.82 tons of HCFC consumption has been phased out, reducing greenhouse gas emission by 19,613 tons CO2 eq. The implementation of the project followed the rules and procedures of National Execution (NEX). The Performance Based Payment (PBP) mechanism was applied for the implementation.

1.1 Background

The major applications of HCFCs within the solvents sector in China include cleaning in the Medical, Metal (Compressors), Metal (Other), Electronics (LCD), Electronics (Precision), Electronics (Other) and Formulated Solvents sub-sectors. According to survey statistics, the HCFC consumption in the Solvents Sector in China was 4,394 metric tonnes HCFC-141b in 2009.

The Medical Cleaning Applications sub-sector is important from a human health perspective and consumed about 1,700 metric tonnes of HCFC-141b in 2009, representing about 39% of the overall solvent sector consumption. The sub-sector manufactures a range of products that are applied widely and involve more than 400 enterprises. Since 1980s, along with China's rapid economic development, the sub-sector has made great progress and

maintained an average annual growth rate of over 15%, and China has, thus, become the world's leading medical macromolecular product manufacturer. According to statistics, in 2009, the gross sales in the sub-sector exceeded US$ 1.5 billion, 16% higher in real terms than a year earlier. The main products manufactured in this sub-sector include syringes, infusion sets, blood transfusion sets, various puncture instruments (e.g., hypodermic needles, scalp vein sets, blood collection needles, intravenous canulae, puncture needles, biopsy needles, etc.), catheters and other sanitary materials. The devices manufactured are siliconized to reduce friction and the patients' pain; in addition, the silicification tooling used in the manufacturing of these devices needs regular cleaning, so as to prevent the tooling stained with silicone oil from polluting the joints of puncture instruments. The sub-sector comprises a large number of SMEs with limited access to alternative technologies for HCFCs and their viability depends upon accessing suitable alternative technologies at the earliest. For these reasons, China has prioritized this sector and sub-sector for early interventions to meet the 2013/2015 targets.

To work out a cost-effective and sustainable alternatives to HCFC-141b technology that could be implemented in the large number of predominantly SMEs in the Medical Cleaning Applications sub-sector, the Solvent Demonstration project was prepared and submitted for the consideration at the 64th Meeting of the Executive Committee after due review and endorsement by the Government.

1.2 Silicification and its tooling cleaning process with HCFC-141b

Puncture instruments, such as medical needles, need to be coated with a layer of silicone oil on the blade and the tube. This process is called silicification. The purpose of silicification is to reduce frictional resistance and the patients' pain when the needle pierces the skin. This process is completed at the silicification working station of assembly machines.

Silicification tooling refers to a special kind of working station utensil (see pic1) that is used on the assembly machines for puncture instruments. Needle assembly and silicification must be completed on this tooling. Each strip-shaped tooling contains 50 steel needle seats with unfinished needles. Each needle assembly machine usually has at least 600 such tooling. When the needles are siliconized, the tooling is contaminated by silicone oil, so it is necessary to clean the tooling on a regular basis. Otherwise, the silicone oil will stick on the inner bore of needle hubs and the outer surface. Accordingly, when needles are put on syringes, they will fall off automatically or the connection may not be secure. In case of continuous production, each tooling needs cleaning every 15-20 days.

The original single-tank open-type ultrasonic cleaning machines are located in KDL's Class 100,000 clean room which was built in May 2005. Each cleaner could clean about 200,000 stripe-times of silicification tooling every year; in 2009, the consumption of KC-3000C[1] was about 33.6 tonnes (equivalent to 21.84 metric tonnes of HCFC-141b). The machines in current use are all single-cylinder ultrasonic cleaners. Workers are needed to load and unload the materials. After cleaning, the materials have to be put on the shelf for drying. There are mainly 4 processes, i.e. loading, cleaning, drying and unloading. These machines will need to be modified due to the following:

- The machines are not closed, so the operators will unavoidably have contact with solvents and inhale solvent vapors;

-There is no explosion-proof safety features and thus, the process, as set-up currently, is not suitable for the alternative solvent with slight flammability. Further, there is no solvent recovery system and as a result, the consumption is high. The cost will increase when using the alternative solvent with higher unit price.

[1] KC-3000C's main ingredient is HCFC-141b (65%) and others, much safer and better than HCFC-141b for the needle silification.

1.3 Technology Choice

Some of the zero-ODP alternatives to HCFC-141b currently available for this application are listed below:

Solvent Option	ODP	GWP	Remarks
HFC-4310	0	1,300	HFC-4310 is one of the Vertrel® series solvents launched by the US DuPont Company, with decafluoropentane as the principal component. It is non-toxic and non-flammable. As a silicone oil solvent, the boiling point, surface tension and viscosity index are ideal. If HCFC-141b is taken as the benchmark for comparison, HFC-4310 shows poor effects of CO_2 emission reduction and its toxicity is higher than HCFC-141b. Moreover, it is expensive and the price is as high as US$ 70/kg
HFC-365mfc	0	840	While this option offers good solvent properties, with respect to HCFC-141b, it has a higher GWP. It is also flammable in the range of 3.5% - 9% by volume in air, thus safety becomes a significant barrier for adoption. It is also more expensive than HCFC-141b with a cost of about US$ 22/kg.
KC-3000	0	750	KC3000 is a HFC-365mfc-based mixed solvent. It is compatible with most kinds of materials, not easily flammable, non-toxic and volatile and its chemical properties are stable. Its inadequacy is that it has a certain degree of flammability. The cost is about US$ 12/kg.
HFE-7100	0	480	HFE-7100 is a fluoride based solvent launched by 3M® Corporation. It is non-toxic, non-flammable and has a relatively low GWP. As a silicone oil solvent, its boiling point, surface tension, and viscosity index are ideal. Although its boiling point is higher than HCFC-141b, its latent heat of evaporation is 40% lower than HCFC-141b, therefore, when the needle tube and the outer sleeve are silicified, the solvent is easily volatile, leaving little residue. Its surface tension is 26% lower than HCFC-141b, but its silicone oil dispersion and coating properties are better than HCFC-141b. Its GWP is lower than HCFC-141b. However, its main disadvantage is its cost, which is in the range of US$ 60/kg.
KC-6	0	<20	KC-6 is a new generation of environment-friendly medical silicone oil thinner developed by Beijing Aerospace Technology Innovation Co., Ltd., in light of the actual situation of China's medical device industry. It is a combination of Siloxanes, Isoparaffin, etc. Its shortcomings are that it has certain degree of flammability, a high boiling point, and is less volatile as compared to the current technology. Its cost is favorable at about US$ 6.8/kg.

There are other alternatives available or under development. But due to their high GWP, flammability, performance, implement ability or costs, they were not considered to be viable. On the other hand, while adopting KC-6 as an alternative solvent, one should consider the following impacts:

Safety

KC-6 is flammable, although it has a higher flash point. When it is used by the medical device industry in clean rooms, particular attention needs to be given to safety due to the accumulation of solvent vapors, and necessary precautions have to be taken. With those measures taken, its flammability could be controlled.

Silicification performance

KC-6 has a higher boiling point; after silicification, its evaporation rate will be slower than HCFC-141b. In accordance with the current practice, as soon as the needles are silicificated, they will be turned upside down. Thus, if the solvent cannot be evaporated in time the silicification fluid will flow to the needle hub, causing the absence of silicone oil in the needle tip and the contamination of the needle hub and silicification tooling. In order not to reduce the output, air dryers will need to be installed on the assembly line.

Biocompatibility and drug compatibility

Puncture instruments are devices that enter human tissues and may come into contact with blood. As KC-6 is a mixed solvent, the biocompatibility and drug compatibility of Isoparaffin, should be confirmed for patients' safety.

2. Project Implementation

The project was approved by 64th Executive Committee meeting in 2011 at a funding of US $ 557,667. Project implementation started in 2012, all the progress milestones required by the contract were reached and verified by the end of 2013. The project successfully passed national acceptance in December, 2013.

This demonstration project proposed to modify a needle assembly line and an ultrasonic cleaning line at Zhejiang Kindly Medical Devices Co. Ltd. to provide a demonstration of KC-6 technology.

According to the project implementation plan, the following activities were carried out:

I. Equipment redesign and installation

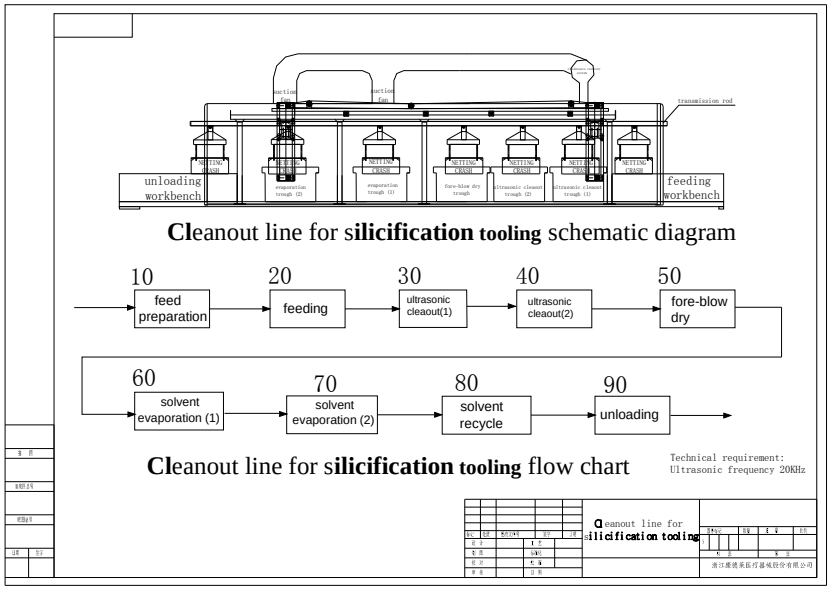
1. Ultrasonic cleaning line

In order to realize mechanized operations with minimum operator interference, human errors and exposure, the silicification tooling has a strip shape; when it is cleaned, a container is needed to hold it. Each container can hold 30 pieces silicification tooling. Thus a mechanical lifting device, instead of the manual operation of an operator, can be used to transfer automatically the containers between different working stations. In this case, the operator will not touch the solvent. These containers are an essential equipment to realize closed and mechanized operation. In addition, the containers must be designed not to block ultrasound penetration. Otherwise, the silicification tooling held within cannot get the impact of ultrasonic, and the effectiveness and efficiency of cleaning will be significantly reduced. The ultrasonic cleaning line was designed based on the following considerations:

Pic1: Silification toolings

Pic2: silification toolings with needles on

- To make the machine fully closed, and prevent operators from contact with solvents.
- To adopt the explosion-proof design, and select explosion-proof electrical appliances and equipment.
- To set up a solvent recovery system, so that solvent vapors in confined spaces and the polluted solvent residue can be recovered in time, so that solvent consumption can be reduced.
- After cleaning with the use of KC-6, an evaluation on the cleaning effects from the aspects of appearance and needle connection firmness needs to be conducted:
  - Appearance evaluation: Wipe the surface of the tooling with white paper, use a 10x magnifying glass to observe the surface of the white paper, and there should be no oil stains.
  - Connection firmness evaluation: Put a needle onto a cleaned silicification tooling, silicize the needle, and use a fastness tester to test its firmness to see whether the product is qualified.



Pic3: process flow chart of cleaning line for silification tooling

The tooling cleaning line is a LBD-6090 JRTF automatic ultrasonic cleaner manufactured by Shenzhen Liboda Technology Co. Ltd., and is composed of a set of equipment of solvent immersion and a set of 13-roller automatic scrubbing equipment and an ultrasonic cleaner which is equipped with 6 tanks. Among them, the former three are heating cleaning tanks, each can hold 30L cleaning agents and work at 50°C usually; the fourth is a gas cleaning tank, which can also hold 30L cleaning agents and work at 80°C usually. The fifth and sixth are drying tanks, which can work at the temperature from room temperature to 120°C; the last is a solvent recovery tank, with a capacity of 30L/h to 50L/h. With good operation flexibility, the working time of each working station of this cleaner could be set from 30 seconds to 60 minutes.

The cleaning for 3 minutes and cold air drying at room temperature could get good cleaning result that met the production requirements. The equipment of solvent immersion is used to soak and pre-clean clamp from the needle assembly line back to the cleaning line. Good cleaning is presented due to long time of turnover and immersion cleaning. The toolings are automatically scrubbed by the scrubbing equipment with 13 rollers to replace manual scrubbing, before they transferred into the ultrasonic cleaner. Of the 13 rollers, the former three and the last four are slow rotating rollers, while the middle six are quick rotating rollers. This scrubbing equipment is controlled through PLC, which is equipped with a set of refrigeration device for the purpose of circulating cooling of cleaning tanks. The field verification results indicated that both the drying speed and the effect of clean were good, could meet the cleaning requirements, and also conform to the specified technical requirements of the demonstration project.

Pic4: the needle-making clamp cleaning line

KC-6 清洗产品的链接牢固度记录表

时间	规格	数量	合格数	判定	备注
2014.5.12	22G	100	100	合格	
2014.5.13	22G	100	100	合格	
2014.5.14	22G	100	100	合格	
2014.5.15	22G	100	100	合格	
2014.5.16	22G	100	100	合格	
2014.5.17	22G	100	100	合格	
2014.5.19	22G	100	100	合格	

注:牢固度标准为 40N 不脱落。

Pic5: Link reliability test data

KC-6 清洗产品的清洁度记录表

时间	规格	数量	与注射器配合无脱落数	有无油污	判定	备注
2014.5.12	22G	100	100	无油污	合格	
2014.5.13	22G	100	100	无油污	合格	
2014.5.14	22G	100	100	无油污	合格	
2014.5.15	22G	100	100	无油污	合格	
2014.5.16	22G	100	100	无油污	合格	
2014.5.17	22G	100	100	无油污	合格	
2014.5.19	22G	100	100	无油污	合格	

Pic6: cleaning quality test data

After modification, the silicification tooling cleaning lines has been adjusted according to the new features of KC-6 to meet health, safety and environment requirement.

The needle assembly line

The original needle assembly line includes eight major production processes, i.e. feeding of needle hub, assembly of needle canula, gluing adhesive, curing (in a tunnel oven), silicification, feeding of protective cap, pressing protective cap, and unloading products. Each of these processes is accomplished through special purpose-built automatic machines and devices of 1997-1998 vintage.

Pic7: Needles

Pic8: Needle assembly line

Pic9: Silicification working station

Pic10: Needles Silicification by hand

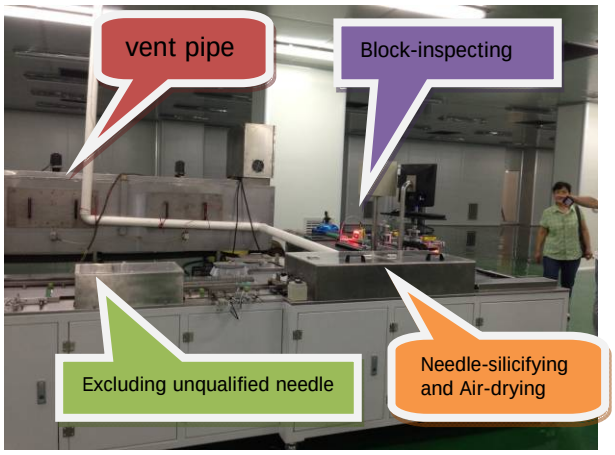
Process Changes

KC-6 has a higher boiling point and slight flammability. To address these issues, the demonstration project involved modification of production lines, process adjustments, silicification fluid management, evaluation of needle silicification effects and the effects of silicification tooling cleaning, the confirmation of biocompatibility and drug compatibility, as well as related training and technical assistance.

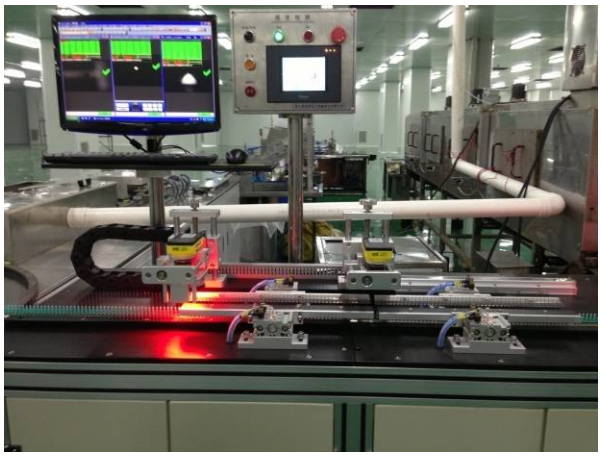
Process Changes Made for Needle Assembly Line
Adjustment of the silicification process Since KC-6 has certain flammability, in order to control the concentration of the clean room within flammable limits, KDL installed an explosion-proof local exhaust ventilation hood near the silicification tank to discharge as much as possible the volatile solvent vapors outside the clean room. All local ventilation hoods that have been installed in the clean room can be connected together to form a ventilation system during the entire phase-out in the enterprise in the future.
Addition of vacuum dryer As KC-6 has a higher boiling point, the solvent cannot be volatilized in a timely way. So the silicification fluid will flow to the needle hub, causing the absence of oil in the needle tip and the pollution of the needle hub and silicification tooling. Therefore, in order to accelerate evaporation, a vacuum drying process was added after the silicification process.
Technological adjustments Due to the use of a new solvent, the technical process of the whole assembly line has to be adjusted moderately: ***Production process***: Because of the addition of the vacuum drying process, the operation speed of the assembly line, the quantity of tooling allocated and the work-piece making sequence were adjusted accordingly; ***Ventilation system***: In order to prevent the accumulation of solvent vapors in the clean room, KDL increased the volume of outdoor air for dilution and to add fresh air, so that a positive pressure can be ensured in the purification room.
Management of silicification fluid As a result of using a new solvent, KDL adjusted the silicification fluid management methods, including: compounding methods, the indicators and methods for controlling the concentration of fresh silicification fluid and the concentration and control indicators of silicification fluid in the tanks varying with the change characteristics of the duration of silicification, its control methods, testing methods of control indicator and equipment adjustments. A recovery system was built to recover the solvent of the residual silicification fluid that has already lost effectiveness; explosion-proof security measures were taken to achieve a unified storage of the residue.
Evaluation of needles silicification After using the new solvent, the effects of needle silicification was evaluated from two aspects: ***Appearance evaluation***: Evaluate the dispersion of silicone oil, oil amount at the needle tip and the pollution condition of the needle seat; ***Puncture force evaluation***: Use the needle sharpness tester for testing; investigate the magnitude of force, the peak value position and the waveform of force.

The needle assembly line installed

The needle assembly line was installed at the new workshop of KDL, consisting of a needle seat system, a needle tubing system, a gluing system, a drying system, an image-processing system, a block-inspecting system, a needle-silicifying system, an insert-inspecting system, an upper cover system, a needle-removing system, an electric control system and so on. The needle-silicifying system involved in this equipment is well sealed that uses KC–6 as the solvent, in which the tooling can roll over automatically. The volatilized solvent after silicification is pulled to outdoor through the vent pipe on the side of the silicifying tank to address the safety risks. The previous silicifying equipment has the function of silicification and block-checking, while the new equipment adopted the technology of laser and rapid photography, in which the inspection of block will be completed before silicification. That is, the new silicifying system is only responsible for silicification. The new equipment can meet the demand of the production, as for the high automation, high detection sensitivity and reasonable safety precautions judged from the run of the equipment.

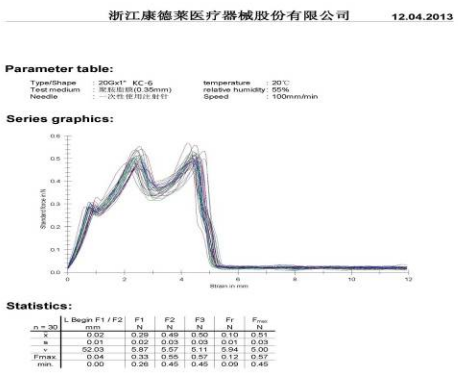


Pic11: Converted needles assembly line

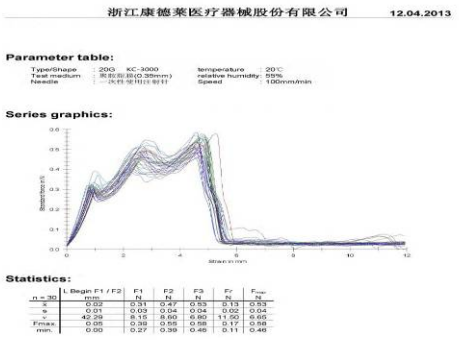


Pic12: Block-inspecting system

When the needle assembly line was put into production, KDL made a lot of tests on the puncture force. For the 0.9mm needles, the puncture force with KC-6 is 0.51N, a little better than that with HCFC-141b (KC-3000), which need 0.53N.



Pic13: Puncture force evaluation with KC-6



Pic14: Puncture force evaluation with HCFC-141b

II. Workshop modification for KC-6

Before all the equipment conversion work of demo project in the new plant, KDL carefully prepared the constructions with more fire prevention materials, fixed a ventilation system in large scale in all the workshops using KC-6, placed the new ultrasonic cleaning line and silification fluid in independent room respectively. All workshops producing needles are furnished according to the Medical Devices Production Standard.

The cleaning line was installed in another building, far away from needles production workshops.

After the workshop modification, KDL applied for the fire prevention inspection of construction project, Medical Devices production license and contaminant discharge license for the responsible administration department, and got the Medical Devices production license on 16 September 2013; got the contaminant discharge license on 10 October 2013; got approved by the local fire prevention bureau on 24 January 2013.


中华人民共和国

医疗器械生产企业许可证

编　　号：浙食药监械生产许20100054号

企业名称：浙江康德莱医疗器械股份有限公司

注册地址：温州市龙湾区永中镇永强路252号

生产地址：浙江省温州市龙湾区永中镇永强路252号；浙江省温州市龙湾区滨海工业园区滨海五道758号

生产范围：第二、三类6815注射穿刺器械；第三类6866医用高分子材料及制品；第三类6877介入器材；第二类6810输液贮外科（骨科）手术器；第二类6841医用化验和基础设备器具***

有效期至：2015年06月13日

法定代表人：孙昌金

企业负责人：方剑家

发证机关：浙江省食品药品监督管理局

发证日期：2010年06月18日

国家食品药品监督管理局统一印制

Pic15: License for Medical devices production


浙江省排污许可证

编号：浙CC2013B0216

单位名称：浙江康德莱医疗器械股份有限公司

单位地址：龙湾区永强路252号

法定代表人（主要负责人）：孙昌金

排放污染物的种类、浓度、数量：（详见副本）

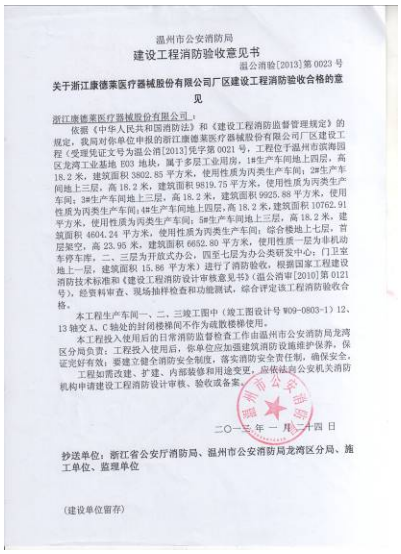
有效期限：自 二〇一三年十月十日 起至 二〇一六年十月十日 止

发证机关：（盖章）

发证日期：二〇一三年十月十日

浙江省环境保护厅监制

Pic16: License for pollution discharge


温州市公安消防局

建设工程消防验收意见书

温公消验[2013]第0023号

关于浙江康德莱医疗器械股份有限公司厂区建设工程消防验收合格的意见

浙江康德莱医疗器械股份有限公司：

依据《中华人民共和国消防法》和《建设工程消防监督管理规定》的规定，我局对你单位申报的浙江康德莱医疗器械股份有限公司厂区建设工程（受理凭证文号为温公消[2013]凭字第0021号，工程位于温州市滨海园区龙湾工业基地B03地块，属于多层工业用房，1#生产车间地上四层，高18.2米，建筑面积3802.85平方米，使用性质为丙类生产车间；2#生产车间地上三层，高18.2米，建筑面积9819.75平方米，使用性质为丙类生产车间；3#生产车间地上三层，高18.2米，建筑面积9925.88平方米，使用性质为丙类生产车间；4#生产车间地上四层，高18.2米，建筑面积10762.91平方米，使用性质为丙类生产车间；5#生产车间地上三层，高18.2米，建筑面积4604.24平方米，使用性质为丙类生产车间；综合楼地上七层，首层架空，高23.95米，建筑面积6652.80平方米，使用性质一层为非机动车停车库，二、三层为开放式办公，四至七层为办公类研发中心；门卫室地上一层，建筑面积15.86平方米）进行了消防验收，根据国家工程建设消防技术标准和《建设工程消防设计审核意见书》（温公消审[2010]第0121号），经资料审查、现场抽样检查和功能测试，综合评定该工程消防验收合格。

本工程生产车间一、二、三竣工图中（竣工图设计号W09-0803-1）12、13轴交A、C轴处的封闭楼梯间不作为疏散楼梯使用。

本工程投入使用后的日常消防监督检查工作由温州市公安消防局龙湾区分局负责；工程投入使用后，你单位应加强建筑消防设施维护保养，保证完好有效；要建立健全消防安全制度，落实消防安全责任制，确保安全。

工程如需改建、扩建、内部装修和用途变更，应依法向公安机关消防机构申请建设工程消防设计审核、验收或备案。

二〇一三年一月二十四日

抄送单位：浙江省公安厅消防局、温州市公安消防局龙湾区分局、施工单位、监理单位

（建设单位留存）

Pic17: Firefight acceptance report


浙江省排污许可证

副　本

单位名称	
单位地址	
法定代表人（主要负责人）	
所在经度	所在纬度
所在流域	GB 区/县域
环境空气质量标准	环境空气质量标准（GB 3095-1996）二级
水环境质量标准	地表水环境质量标准（GB 3838-2002）III类
生态功能区划	
生产（经营）范围	许可经营项目：第二三类6815注射穿刺器械，第三类6864医用高分子材料及制品，第三类6877介入器材，第二类6810输液贮外科（骨科）手术器械加工、制造。一般经营项目：经营进出口业务

有效期限：自 2013年10月1日起至 2016年10月10日

发证机关：（盖章）

发证日期：2013 年 10 月 10 日

Pic18: B**ack-up of License for pollution discharge**

III. Confirmation of biocompatibility and drug compatibility

In 2012, KDL submitted the needles siliconized with KC-6 to National Institutes for Food and Drug Control (NIFDC) to test whether the isoparaffin that remains after needle solidifications and cleaning will have an impact on biocompatibility and drug compatibility. In July 2013, NIFDC provided testing report indicating the Needles siliconized with KC-6 are well in seven major indicators according to China pharmacopeia. The result will also benefit other medical equipment device production enterprises, saving their testing time and money when utilizing this substitutes.

The durability evaluation between KC3000C, KC-6 and national standard is given in the table below.

Date	Scale	National standard（GB15811）on durability	KC3000C		KC-6		Result
			Number of needle samples	Non -qualified	number of needle samples	Non -qualified	
2014.5.12	22G	Not break off under 40N	100	0	100	0	qualified
2014.5.13	22G		100	0	100	0	qualified
2014.5.14	22G		100	0	100	0	qualified
2014.5.15	22G		100	0	100	0	qualified
2014.5.16	22G		100	0	100	0	qualified
2014.5.17	22G		100	0	100	0	qualified
2014.5.19	22G		100	0	100	0	qualified

The puncture evaluation between KC3000C, KC-6 and national standard is given in the table below.

No.	Scale	National standard（GB15811）on puncture（N）	KC3000C	KC-6	Result
1	22G	≤0.85	0.63	0.57	qualified
2	22G	≤0.85	0.59	0.55	qualified
3	22G	≤0.85	0.56	0.56	qualified
4	22G	≤0.85	0.55	0.57	qualified
5	22G	≤0.85	0.64	0.59	qualified

KDL’s product has been approved by CE certification by EU and FDA factory verification.

In 2013, FECO signed HCFC-141b phase out contracts with 6 Medical Devices production enterprises, all of them selected KC-6 as suitable substitute for HCFC-141b.


中国食品药品检定研究院

检验报告

报告编号：QH201300782

检品名称：一次性使用无菌注射针

生产单位：浙江康德莱医疗器械股份有限公司

检定目的：合同检验

检验依据：约定方法

中国食品药品检定研究院检验报告

报告编号：QH201300782　　共 1 页，第 1 页

检品名称	一次性使用无菌注射针	样品编号	QH05022012015 68
生产单位	浙江康德莱医疗器械股份有限公司	批　号	0051
供样单位	浙江康德莱医疗器械股份有限公司	规　格	0.7×32mm
检验目的	合同检验	型别/型号	/
检验项目	部分检验	包装规格	1 支/袋
收样日期	2012 年 11 月 27 日	有效期至	2015 年 10 月
检品数量	200 袋	签封数量	/
检验依据	约定方法		

检验项目	标准规定	检验结果
药物相容性		
地塞米松磷酸钠	样品与空白对照针头相比，药液浓度比应在 90%～110%之间	93%，103%，97%，96%，96%
盐酸布比卡因	样品与空白对照针头相比，药液浓度比应在 90%～110%之间	101%，100%，99%，98%，102%
无菌	应符合无菌规定	符合规定
热原	应无热原反应	符合规定
细胞毒性	应不大于 1 级	0 级
皮内刺激	应无皮内刺激反应	无皮内刺激反应
皮肤致敏	应无皮肤致敏反应	水浸提：无皮肤致敏反应 油浸提：无皮肤致敏反应
急性全身毒性	应无急性全身毒性	水浸提：无急性全身毒性 油浸提：无急性全身毒性
溶血	溶血率应≤5%	0%

以下空白

检验结论	本品按约定方法检验，上述项目符合规定。		
授权签字人		签发日期	2013 年 7 月 25 日

Pic19: Report biocompatibility and drug compatibility

IV. Demonstration

In July 2013, KDL technical manager was invited by UNDP to introduce how this demo project was implemented during the technology workshop on HCFC phase-out alternative technologies.


Pic20: Medical Device Production enterprise representations visited converted equipment by demo project

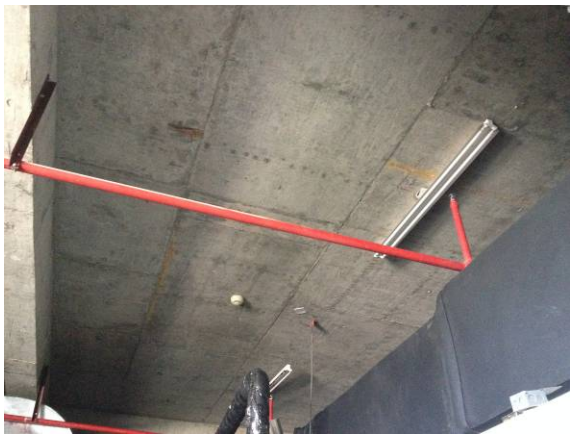

Pic21: Workshop on HCFC-141b phase-out project implementation progress, Zhejiang Wenzhou, 31, July 2013


Pic22: Solvent KC-6

V. Safety measures

With proper hardware for safety, the cleaning line was equipped with a central ventilation system above the whole line, as well as a refrigeration recycling system beside it. An independent ventilation system has been installed to discharge the solvent volatilizing from the silicifying system to outdoor, which increases the safety factor. On the other hand, KDL has formulated fire emergency plans for the two lines. These all can meet the requirements of the demonstration project.

Pic23: Concentration detector



Pic24: firefighter pipes and vent pipe

Management of silicification fluid

As a result of using a new solvent, it is necessary to adjust the silicification fluid management methods, including: compounding methods, the indicators and methods for controlling the concentration of fresh silicification fluid and the concentration and control indicators of silicification fluid in the tanks varying with the change characteristics of the duration of silicification, its control methods, testing methods of control indicator and equipment adjustments. A recovery system was built to recover the solvent of the residual silicification fluid that has already lost effectiveness; explosion-proof security measures are taken to achieve a unified storage of the residue.

Pic25: Special room for silicification fluid management with vent pipe and firefight pipe

Process and safety training

Training was provided to the production, installation and maintenance personnel on the physical and chemical properties of KC-6, technical adjustments of modification processes and added processes, silicification fluid management, silicification effects, methods for cleaning effect evaluation, methods of operating newly-added equipment, machine operating parameters, machine maintenance procedures, precautions and safety measures, etc.

Process and safety training were provided to the manufacturing, installation and maintenance personnel. It was verified that the internal technical acceptance were completed and technical commissioning and relevant personnel training were finished.

KDL invited KC-6 technical service to introduce matters needing attention in different stages of production and silification liquid management.


Pic26: Training workshop for workers

3. Management

The project was under the overall management and coordination of the Foreign Economic Cooperation Office, Ministry of Environmental Protection of China. UNDP was the implementing agency for the project, which provided international coordination and technical assistance.

The project employs the Performance-based Payment (PBP) mechanism in its implementation. Under the PBP mechanism, the enterprise tasked with carrying out the conversion would play the role as a key executer, which is responsible for all the activities related to the conversion. The procurement was organized fully in line with the marketing principle ensuring cost-effective and timely installation of equipment for KC-6 based manufacturing operations.

FECO and UNDP were not involved in the procurement activities of the enterprise by any means. FECO made payment to the enterprise in tranches for the costs of procurement and conversion, at agreed payment dates given in the payment schedule, and when milestones prerequisite for the tranche have all been achieved on time.

Before each payment, FECO invited independent experts to verify whether the performance for each milestone that the payment is contingent on has been satisfied. The verification reports were submitted and accepted by UNDP as the main supporting documents for requesting the installment of payment.

During project implementation, FECO and UNDP organized 5 verification missions combined with monitoring and evaluation at KDL factory - once in 2011, once in 2012 and 3 times in 2013. The experts group included technology experts and finance experts, FECO staff and UNDP staff as well. The experts team traced the project implementation situations, evaluated the project technical issues and progress, and verified whether the performance for each milestone of the respective payment has been satisfied. Each verification activity was carried out in a process of planning, preparation, data confirmation, technical material checking, on-the-spot investigation, result confirmation and conclusion.

4. Outcomes

The project was completed and has successfully passed national acceptance in December 2013. The production line is in commercial operations, and the IOC has been disbursed to the enterprise in April.2014. The suitability of KC-6 technology as a viable replacement for HCFC-141b as a solvent in the manufacture of needles at Zhejiang KDL was established.

The following are the important outcomes of the project.

- The enterprise completed the redesign and production process of the needle assembly line and ultrasonic cleaning line in 2012.
- Equipment for modification of ultra-sonic cleaning line and a half-automatic needle assembly line was procured in 2012.
- Needle assembly line and ultra-sonic cleaning machine converted and verified in 2013.
- Demonstration was presented to other Medical Devices Production Enterprises in 2013.
- Technical commissioning was completed successfully and relevant personnel were trained in 2013.
- The project successfully passed national acceptance in December 2013.

5. Technical performance

- KC-6 has a zero ODP and very low GWP, thus it is ozone-layer friendly but also climate-friendly.
- KC-6 is a mixture, whose components are easily available on the market at favorable costs through domestic production;
- KC-6 has a higher boiling point than HCFC-141b; as a solvent, it is less volatile and therefore has less dissipation and result in less consumption;
- KC-6 exhibits good solvent properties for silicone oil, removing silicone oil from contaminated tools quite easily. The compound is clear and transparent, with good coating quality on the surface of needles;
- Due to its chemical stability and high flash point and boiling point, its comprehensive emission reduction and environmental benefits turn out to be much better than the HCFC-141b-based solvents currently use;
- The compound can be used as both the silicone oil thinner and the cleaning agent, therefore, allows relatively easy management of procurement, storage and handling;
- The KC-6 has been applied to other several Medical devices production enterprises in China. Thus, the performance has potential to be promoted.

6. Project management and monitoring

6.1 Project progress

The project was implementing smoothly according to the program schedule, and was completed by the end of 2013. It successfully passed national acceptance in December 2013. The capacity of the production line has been converted to use substitute solvent.

Each of milestones was achieved and verified, the details are as follows:

Milestones		Status
1st	Signing of the contract	FECO and the enterprise signed contract in March 2012
2nd	KDL sign the procurement contracts with conversion equipment suppliers	Finished in October 2012
3rd	Conversion equipment was installed in KDL	Finished and verified in July 2013
4th	The trial run of conversion equipment was verified by expert team	
5th	National acceptance	Finished and verified in December 2013
6th	Submit half-year run report and financial vouchers to FECO	Finished and verified in April 2014

6.2 Conversion cost

Total Project Costs

The total contract amount signed with the enterprise is US$ 510,662 including ICC US$ 305,046, and IOC US$ 205,616.

Incremental Capital Costs

The actual incremental capital costs for conversion was US$ 360,005 among which US$ 352,051 was funded by the MLF, and the US$ 7,954 was co-financed by the enterprise. The details of ICC are as follows:

No.	Item/Description	Grant funds (US$)	Counterpart funds(US$)	Actual cost
1.	**Needle assembly line modifications(** Local exhaust device; air dryer; Conveyor modifications; Intermediate inspection bench; Installation and commissioning; Electronics adjustment and debugging**)**	**96,763**	**0**	**96,763**
2.	**Process Adjustments(**Additional silicification tooling, Conveyor to transfer workpieces from silicification tooling to dryer)	**10,884**	**7,954**	**18,838**
3.	**Silicification fluid management** (Closed liquid mixer ;Safety features (alarm, ex-proof electricals); Digital rotary viscometer; Residue processor)	**42,950**	**0**	**42,950**
4.	**Silicification tooling line modifications (**Modification of ultrasonic cleaning line and mechanization; Workpiece loading container; Solvent recovery system; Installation and commissioning; Electronics adjustment and debugging)	**121,845**	**0**	**121,845**
5.	**Performance evaluation (**Puncture testing; Biocompatibility testing; Drug compatibility testing (statutory authorities) ;Silicification form evaluation; Silicification durability evaluation)	**27,103**	**0**	**27,103**
6.	**Other(**Design and technical expert fees, technical assistance Process; trials Process and safety training Documentation; reporting and information dissemination (UNDP) ;Project management(FECO) ;External monitoring and experts verification)	**52,506**	**0**	**52,506**
	Total	**352,051**	**7,954**	**360,005**

Note: Contingency of USD15,000 was mainly disbursed for process adjustment and silicification tooling line modification (smoke detector and alarming system). The amount of USD15,000 is already included in these two line items.

Incremental Operating Costs

The approved total incremental operating costs calculated for one-year duration amount to US$ 205,616. The production line is in commercial operations and the IOC has been disbursed to enterprise in April.2014. The actual amount of incremental operating costs was US$ 217,600, US $ 205,616 was from bilateral cooperation of the Government of Japan. US $ 11,984 was co-financed by the enterprise.

The cost for the baseline HCFC-141b based two-stage systems are summarized as below:

1. HCFC-141b price is US$ 2.66/kg
2. KC-6 price is US$ 6.8/kg (*exchange rate changes a lot from 2009 to 2013*)

Incremental Operating Costs

Item	KC-6 consumption in one year(kg)	HCFC-141b consumption in one year(kg)	Reasons
An ultrasonic Cleaning line	25,000	21,840	Tooling cleaning times frequency increased, from one time in half a month into one time in a week
A needle Assembly line	7,000	5,980	Air dryer after silification speeds solvent volatilization, the dryer took more solvent than actual coated in needle
Total	32,000	27,820	

7. Impact

Environmental Impact

The HCFC-141b consumption during 2009 at Zhejiang Kindly Medical Devices Co. Ltd. was 27.82 metric tonnes.

Substance	Quantity	ODP	GWP	CO_2-eq emissions
HCFC-141b	27.82	0.11	725	20,169
KC-6	32	0	20	640
Impact		**(3.06)**		**(19,529)**

Based on the above, the successful implementation of this project will result an annual reduction of minimum 3.06 ODP tonnes and annual direct emission reductions of 19,529 tonnes CO_2-eq.

Results

The successful implementation of this project resulted in the following:

(a) Sustainable reductions in HCFC consumption in the Solvents sector in China of 3.1 ODP tonnes, contributing to China's compliance with the 2013 and 2015 control targets

(b) Demonstration and availability of an environmentally safe and cost-effective alternative for enabling replication of this technology in similar applications and enterprises in the Medical Cleaning Applications sub-sector in China. It must be noted that results of KDL project are already being used by companies in China for phasing-out HCFC-141b in select solvent applications with KC-6.