

File Name: Clinical evaluation report

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# Clinical Evaluation Report

Clinical Evaluation according to MEDDEV 2.7.1 rev.4

**Product Name:** Disposable Acupuncture needles

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**Suzhou HuaLun Medical Appliance Co., Ltd.**

**Content**

# Suzhou HuaLun Medical Appliance Co., Ltd.

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### 1. Summary

In order to ensure that the products of our company in clinical stability and safety guaranteed when using, So for the safety of the product performance and material for clinical evaluation.

We conduct clinical evaluation methods include data generated through literature search and equivalent device. We use literature to illustrate the safety and effective of the products, and provide a justification of the equivalency for the equivalent device to evaluate the safety and effective of the product.

### 2. Scope of the clinical evaluation

- 1) Intended purpose and application of the device;
- 2) Manufacturer’s specific claims about clinical performance and safety of device;
- 3) The significance of any risks that remain;
- 4) The data source and type of data to be used in the clinical evaluation.

#### 2.1 Description of device

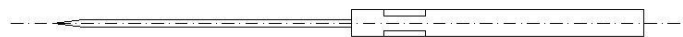
The acupuncture needle consists of the needle body and the needle handle as shown in the diagram and the type diagram in the relevant international and national standard ISO 17218:2014. Press needles are derivatives of the acupuncture needle.



Round handle needle product type figure



Flat handle needle product type figure



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## Metal handle needle product type figure

### 2.2 Product structure

- **Needle Body**

The needle body is made of X5CrNi18-9 stainless steel, and the handle is wrapped with the copper wire. The handle is classified into 3 types: the flat, the round and the twisted handle. Our product for export is of the round handle, which is the most popular shape, with the widest applications. The needle body length (I) and the full length (L) of the acupuncture needle are designed according to the relevant international and national standard ISO 17218:2014.

1. **Diameter of needle body:** According to the clinical requirements, there are the following diameters of the needle body: from 0.16 mm to 0.45 mm;.
2. **Acupuncture needle length:** from 13 mm to 150 mm.
3. **Materials of needle body:** The acupuncture needle requires the sharpness, elasticity, tenacity and corrosion resistance, so the X5CrNi18-9 (ISO 15510 and GB/T4240, Stainless steel wire) or other austenite stainless steel wires are chosen, according to ISO17218:2014 . X5CrNi18-9 stainless steel wire is the same material used for the transfusion needle, with biocompatibility and without side effect to human body.

- **Needle handle**

The handle is the part for the doctor to hold and turn the acupuncture needle during use. It is manufactured with the copper wire as specified in the national standard ISO 17218:2014, indicating the correlation between the needle body diameter and the diameter of the copper wire of the handle.

### 2.3 Intended use

Piercing the skin used in acupuncture treatment, pain relief and release.

### 2.4 Contraindication

The acupuncture therapy is used for a wide range of indications, covering the internal medicine, surgery, gynecology, pediatrics, ENT and other disciplines. The following

provide the precautions during the needle treatment, not necessarily the contraindications:

- Do not use it for the patient with excessive fatigue, starvation or mental stress, but use it after recovery.
- For patients of poor physical condition, perform the treatment in lying position, to avoid excessive stimulation.
- Do not use it at the blood vessel to avoid bleeding, nor for the patient with spontaneous hemorrhage or continuous bleeding after injury.
- Do not use it at the site with infection, ulcer or scar.
- Pull out the needle when the patient feels the electrical sensation or significant pain, or the needle tip touches the rigid tissue.
- For eyes, neck, breast and back, rib or other acupoints, properly control the angle, direction and depth of inserting.
- Do not use it at the acupoints of the lower abdomen or the sacrum of women in pregnancy within 3 months; and not at upper abdomen or the points with high stimulation (as Hegu, Sanchujiao, etc.) for women in pregnancy over 3 months. Use cautiously for those with the history of habitual abortion. Do not use it for women during menstruation, except for regulating menstruation.
- Do not use at the acupoints at the vertex of infants with fontanelles not closed. Do not insert the needle so quick or retain the needle when treating infants or children as they may not be cooperative.
- For other conditions not frequently seen, the patient shall inform the doctor timely.

## **2.5 Safety or performance claims**

The safety of device had passed verification by the ISO 17218:2014 test reports, and we have complete the Biological compatibility evaluation report. So the material which contact with patient is safety. The quality assurance system had got the certification that compliance with the requirement of ISO13485, which ensure that the development and manufacture activities are under control and trustable.

## **3. Clinical background current knowledge, state of the art**

The acupuncture is an important part of the Chinese medicine and it has become an integral part of the world medicine. Based on the exploration and accumulation of the

acupuncture theories, therapeutic experience, methods and skills for thousands of years, the medical community in China and the world continues to develop and innovate the theories and applications of the acupuncture needle, and expands and promote the use of the acupuncture needle. The acupuncture needle evolved through the stone needle, iron needle, copper needle, gold needle, silver needle and others in the history, and each time of change in the materials brought forth the significant development of the acupuncture therapy. Japanese manufacturers first adopted the stainless steel wire in producing the acupuncture needle in the 1930s, ushering in the new stage of the manufacture of the needle body. Compared with other materials, the stainless steel acupuncture needle features the following characteristics:

- (1) Excellent tenacity for inserting to deep acupoints;
- (2) Sharp and smooth needle tip and body, to insert smoothly and reduce pain;
- (3) Good corrosion proof;
- (4) Available for producing the small filiform needle and super long needle.

In the recent decades, the Disposable Acupuncture needles were manufactured with the stainless steel wire in China, and with the development of the metallurgic technologies, the national standards provide the strict requirements on the designation and chemical composition of the stainless steel wires used for Disposable Acupuncture needles, e.g. 1Cr19Ni9 in the beginning of the 1980s, 1Cr18Ni9 and 0Cr19Ni9 in 1987, and 0Cr19Ni9 and other austenite stainless steel wires in 1994.

From the middle of 1980s, the Disposable Acupuncture needles are classified into the sterile and the non-sterile types. We are now manufacturing the sterile Disposable Acupuncture needles, with the BOPS sheet unit pack heat sealed with the dialysis paper, to ensure the product is sterile within the 3-year shelf life.

The world medicine is now changing from the pure biological medicine mode to the integrated biological-social-psychological medicine mode, consistent to the characteristics and principles of the traditional Chinese medicine focusing on the wholism, diagnosis and treatment on the basis of an overall analysis of the illness and the patient's condition, and, consideration of the social environment and psychological factors. In recent years, the health of people is endangered by the toxic and side effects of chemicals, in addition to the environment pollution and the ecological imbalance; the

hospital-acquired and drug origin diseases increase continuously, and there are also the changes of the disease spectrum, coming of the senile society and many other problem, so people gradually lay the hope on the modern application and development of the traditional medicine and drugs. A fashion is gradually formed calling on people to return to nature, adopt the traditional therapy and advocate the use of the naturally occurring drugs, and it has become the general trend of the current medical development. The strong demand for the traditional medicine and the naturally occurring drugs in the world show the opportunities of the development of traditional Chinese medicine, especially the acupuncture therapy, and the great social benefits and the potential economic benefits.

Who proposed to vigorously develop the system medicine, and Dr. Hiroshi Nakajima, the former director general of WHO, announced “the acupuncture has become an important part of the world medicine” in Geneva and Paris in 1990 (China News of Traditional Chinese Medicine, front page, May 16, 1994) , showing the unprecedented understanding and support of WHO for the traditional medicine.

Our single use sterile acupuncture needle meets the ISO17218:2014 and GB2024-94. The needle body is straight, round, smooth and sharp, with excellent elasticity, tenacity and strength; and the tip is round and regular, without bur, smooth for inserting.

### **3.1 Data appraisal methods from literature search**

Preliminary screening is based on intended use and operation principle of the device in question and scope of clinical evaluation. According to the keyword of Disposable Acupuncture needles search from the literature sources such as ScienceDirect, NCBI.

Second, by reading the summary of the literature, remove the duplicate documents, screening the literature relate to the effectiveness and safety of Disposable Acupuncture needles.

Third, by reading the full text of the literature, remove the literature that not suitable for clinical evaluation, and using following appraisal Criteria for Data Contribution, finally select representative literature according relate to the effectiveness and safety of Disposable Acupuncture needles.



## 3.2 Literature sources used to identify data

- scientific databases – bibliographic

Sources: ScienceDirect, NCBI

Justification: The ScienceDirect and NCBI have plentiful documents for the general information about the clinical data of Disposable Acupuncture needles, ScienceDirect is a high quality academic journal database and NCBI is a large scale integration of information resources, so the rich contents and high quality resources is enough for our clinical evaluation.

- adverse event report databases

Sources: MAUDE, CFDA website, MHRA

Justification: MAUDE in FDA website is the most famous information source. CFDA website is good information source in China. MHRA is List of field safety notices (FSNs) of UK.

### 3.2.1 Database search details

#### 3.2.1.1 ScienceDirect

Key word: Acupuncture Needles 8066

#### 3.2.1.2 NCBI

Key word: Acupuncture Needles 1021

#### 3.2.1.3 MAUDE

Key word: Acupuncture Needles

About 0 records meeting your search criteria returned for Disposable Acupuncture needles.

#### 3.2.1.4 CFDA

Key word: 针灸针

There is no record for Acupuncture Needles

#### 3.2.1.5MHRA

Key word : Acupuncture Needles

There is no record for Acupuncture Needles

### 3.2.2 Search cycle

From 1990 to Now

### 3.2.3 Medium used

All the literatures used to identify data are searching online, and the search way as follow:

Literature sources	access way
Science Direct	<a href="http://www.sciencedirect.com">http://www.sciencedirect.com</a>
NCBI	<a href="http://pub.NCBI.net/kns/default.aspx">http://pub.NCBI.net/kns/default.aspx</a>
MAUDE	<a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm</a>
CFDA	<a href="http://www.sda.gov.cn/WS01/CL0941/">http://www.sda.gov.cn/WS01/CL0941/</a>
MHRA	<a href="https://www.gov.uk/drug-device-alerts/field-safety-notice-2-to-6-november-2015">https://www.gov.uk/drug-device-alerts/field-safety-notice-2-to-6-november-2015</a>

## 3.3 Selection criteria used to choose articles

Preliminary screening is based on intended use and operation principle of the device in question and scope of clinical evaluation.

Second, by reading the summary of the literature, remove the duplicate documents, screening the literature relate to the performance and safety of Disposable Acupuncture needles.

Third, by reading the full text of the literature, remove the literature that not suitable for clinical evaluation, and using following appraisal Criteria for Data Contribution, finally select representative literature according relate to the performance and safety of Disposable Acupuncture needles.

## 3.4 Literature review objectives

To demonstrate Disposable Acupuncture needles has achieving its intended use and performance during normal conditions of use and that the known and foreseeable risks, and any adverse events are minimized and acceptable when weighed against the benefits of the intended performance, and that any claims made about the device's performance and safety are supported by suitable evidence.

## 4. Device under evaluation

### 4.1 Type of evaluation

Device name: Disposable Acupuncture needles

Device model: Specifications are showed by the needle diameter x needle length .Specifications in detail: according to the needle diameter from  $\Phi 0.16$  mm -  $\Phi 0.45$  mm , the length of the needle from 13 mm - 150 mm.

Manufacturer: Suzhou HuaLun Medical Appliance Co., Ltd.

Address: Shengtian Economic Development Zone, HuangQiao XiangCheng District , SuZhou, 215132 China

### 4.2 Demonstration of equivalence(only when equivalence is claimed)

The products are compared with the similar products of Wujiang City Shenlong Medical Health Product Co., Ltd. which have been listed and approved by CE.

Performance / technical parameters	Our company	Wujiang City Shenlong Medical Health Product Co., Ltd.	Comparison results
Product name	D i s p o s a b l e Acupuncture needles	D i s p o s a b l e Acupuncture needles	Same
CE Certification	CE <sub>0197</sub>	CE <sub>0197</sub>	Same
P r o d u c t Specification	Diameter $\Phi 0.16$ mm- $\Phi 0.45$ mm,Length13mm- 150mm	Diameter $\Phi 0.16$ mm- $\Phi 0.45$ mm,Length13mm- 150mm	Same
Performance 【Hardness , Sharpness , Ra Value, Pressure and Puncture Force 】	ISO 17218:2014 GB 2024-94	ISO 17218:2014 GB 2024-94	same

Intended use	Piercing the skin used in acupuncture treatment, pain relief and release.	Piercing the skin used in acupuncture treatment, pain relief and release.	same
Material	SUS304	SUS304	same
Biocompatibility	ISO 10993-1	ISO 10993-1	Same
Sterilization	EO Sterilization	EO Sterilization	Same
Clinical Use	No adverse event occurred	No adverse event occurred	Same
Adverse events	No	No	Same

It can be seen from the table that the devices have the same in tended use and key performance indicator with similar products.

Our products and similar products, all the products have the same material, have good biocompatibility, and adopt the same EO sterilization. In addition, our products and similar products, has achieved the CFDA certification, both at home and abroad listed so far, there no adverse events occurred.

### 4.3 Clinical data generated and held by the manufacturer

Collecting the device that intended evaluation uses condition after sold, include device fault, complication, adverse event, complaints and the same device adverse event.

My company's products adopt EN ISO7153-1:2001 standard stainless steel material, after years of use completely accords with the requirements of the Acupuncture needles, the material meets the requirement of EN ISO7153-1:2001 with biological compatibility, is no side effect to the person.

My company's products sell well in domestic and Europe, Asia and other countries. From 2012 to now, total sales of 100 million to the Acupuncture needles, never received a customer because of the physical and chemical indicators of our products is unqualified, the pyrogen test is unqualified complaints, such as has not occurred against the background of medical accident customer complaints.

### 4.4 Clinical data from Literature

#### 4.4.1 Literature list for ScienceDirect and NCBI

Refer to Annex I, the literature list for searching from ScienceDirect and NCBI.

#### 4.4.2 MAUDE

The result using key word of MQX to search

5 records meeting your search criteria returned- Product Code: MQX Report Date To: 09/30/2015

New Search <span style="float: right;">Export to Excel   Download Files   help</span>		
Manufacturer	Brand Name	Date Report Received
SEDATELEC	<a href="#">PREMIO 10 MOXA - SEDATELEC</a>	06/25/2015
HELIO MEDICAL SUPPLIES	<a href="#">ACUGLIDE</a>	06/04/2014
Unknown Manufacturer	<a href="#">ACUPUNCTURE NEEDLE</a>	05/16/2013
Unknown Manufacturer	<a href="#">DBC SPRINGTEN 0.25X30</a>	10/30/2008
Unknown Manufacturer	<a href="#">KINGLI ACUPUNCTURE NEEDLES</a>	08/13/2008

#### 3) The result using key word of MQX to search

Recalls									
	2007	2008	2009	2010	2011	2012	2013	2014	2015
Class I	0	0	0	0	0	0	0	0	0
Class II	0	1	0	0	0	0	0	0	0
Class III	0	0	0	0	0	0	0	0	0

Recalls			
Manufacturer	Recall Class	Date Posted	
1	<a href="#">Marknew Products</a>	II	Jan-04-2008

#### Summary:

There are many Disposable Acupuncture needles trials in the database. The clinical trials use method of Disposable Acupuncture needles, There are no adverse information for Disposable Acupuncture needles products. That means The Disposable Acupuncture needles is long standing technology. But there is not a clinical trial combination Disposable Acupuncture needles.

#### 4.4.3 CFDA

No results from CFDA for the adverse database.

#### 4.4.4 MHRA

Key word : Acupuncture Needles

There is no record on Acupuncture Needles on MHRA

## Alerts and recalls for drugs and medical devices


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## Annex I Literature screen results

N o.	Literature name	Res sourc irect	Author	Journal name	Publ ishe	the introduction of author
	Nausea Control by Needling at Acupuncture Point Neiguan (PC6) During an Intraoral Impression-Taking Procedure	Scie nceD irect	Vera Lucia Rasera Zotelli*, Ca 'ssia Maria Grillo,  Maria da Luz Rosa rio de	Journal of Acupunctu re and Meridian Studies	24 June 2014	Vera Lucia Rasera Zotell, Corresponding author. Community Dentistry Department, Piracicaba Dental School, University of
	Cluster headache in an elderly patient treated with neurofunctional acupuncture a case report	Scie nceD irect	Julio Cesar Rigo <sup>a</sup> , Claudio Couto <sup>b</sup> , Roberta Rigo Dalla-	Acupunctu re and Related Therapies	18 Febr uary 2014	<sup>a</sup> Pontifícia Universidade Católica do Rio Grande do Sul, Brazi <sup>b</sup> Universidade Federal do Rio
	Effect of Zusanli (ST.36) Electroacupuncture at Two Frequencies on the Bioavailability of <sup>99m</sup> Tc-Sodium Pertechnetate and on Labeling of Blood Constituents in Rats	Scie nceD irect	Vasco Senna-Fernandes  etc.	Journal of Acupunctu re and Meridian Studies	2009	Pós-Graduação de Ciências Médicas (PGCM), Universidade do Estado do Rio de Janeiro (UERJ), Rio de Janeiro, Brazil, Departamento de Biofísica e Biometria, Instituto de Biologia Roberto Alcântara Gomes (IBRAG), UERJ, Rio de Janeiro, Brazil
	Effect of Acupuncture Combined with Blood-letting by a Three-edged	Scie nceD irect	ZHAO Ji-ping etc.	Journal of Traditional Chinese Medicine	June 2010	Department of Acupuncture, Dongzhimen Hospital, Beijing TCM University

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	Does the effect of acupuncture depend on needling sensation and manipulation?	ScienceDirect	Yu-Jin Choi etc.	Complementary Therapies in Medicine	21 February 2013	Department of Neuropsychiatry, College of Korean Medicine, Kyung-
	Prurigo nodularis after acupuncture	ScienceDirect	Timothy Hermosura Almazan,	JAAD Case Reports	2015	the Division of Dermatology, City of Hope
	Effect Of Acupressure On Nausea, Vomiting, Anxiety And Pain Among Post-Cesarean Section Women In	ScienceDirect	Huei-Mein Chen etc.	The Kaohsiung Journal of Medical Sciences	April 20, 2005	Department of Nursing, Chung Hwa College of Medical Technology, 89 Wen-Hwa 1st Road, Jen Te
	Acupuncture point injection therapy plus pharmacotherapy for chronic obstructive pulmonary	ScienceDirect	Meaghan E. Coyle etc.	European Journal of Integrative Medicine	September 2015	China-Australia International Research Centre for Chinese Medicine, School of Health Sciences, RMIT
	The Successful Treatment of Pain Associated with Scar Tissue Using	ScienceDirect	Sheng Fang	Journal of Acupuncture and Meridian Studies	24 June 2014	Oriental Medicine Department, Oregon College of Oriental
	Abdominal acupuncture treatment of chronic atrophic gastritis of 26 cases	CNKI	Liang Yao etc.	Journal of Guangxi College of T.c.m	2011-05-18	Attending physician, engaged in external treatment of traditional Chinese medicine clinical
	Neiguan points breathe in breathe out method to treat hiccups	CNKI	Wen-Zhi Wang	Chinese acupuncture and moxibustion	2011	Sanhe yanjiao secondary and tertiary hospital acupuncture, attending physician.



	Local injection therapy combined with acupuncture Needle and acupuncture knife to treat 205 cases	CNKI	He Liangchao	Journal Of Practical Traditional Chinese Internal Medicine	2012	Hubei chibi guantang town hospital
	Acupuncture Treatment of Tuberculous Pleurisy Complicated by	CNKI	Xiao-Dong Zhao	Journal Of Practical Traditional Chinese Internal	2014-10	Shenyang chest hospital of division of regions

#### 4.5 Summary and appraisal of clinical data

The Literature sources used to identify data are ScienceDirect, NCBI, adverse event report databases ( MAUDE, CFDA website, MHRA) for searching the key word :Disposable Acupuncture needles the result show that there are no adverse information for Disposable Acupuncture needles.

Tabulation of the clinical data used in the evaluation

No	Title	Description	Approp iate device	Appr opri ate devi ce	Appr opriat e patie nt	Accept able report/ data collati	Su ita bili ty
1	Nausea Control by Needling at Acupuncture Point Neiguan (PC6) During an Intraoral Impression-Taking Procedure	This study was conducted in Piracicaba, Saõ Paulo, Brazil. The Disposable Acupuncture needles used in the experiments(0.25 mm ×30 mm in size; Qizhou brand; Wujiang City Shenli Medical & Health Material Co. Ltd, Wujiang,Suzhou, Jiangsu, China) were individually	D3  Other device	A1  Sam e use	P1  Applic able	R1  High quality	D3 A1 P1 R1

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2	Cluster headache in an elderly patient treated with neurofunctional acupuncture a case report	in the study, Were used Disposable Acupuncture needles of 0.25 × 40 mm (Wujiang Shenli Medical & Health Material Co. Ltd., registered in Brazilian Health Agency (0428770001) to acupuncture 65-years-old people who suffer from Introduction Cluster headache (CH),the result	D3 Other device	A1 Same use	P1 Applicable	R1 High quality	D3 A1 P1 R1
3	Effect of Zusanli (ST.36) Electroacupuncture at Two Frequencies on the Bioavailability of 99mTc-Sodium Pertechnetate	Through this study, using 0.25×20 mm (Sterile Disposable Acupuncture needles -Wujiang Shenli Medical & Health Material Co., Ltd, China)A study was performed on the effects of stimulation at Zusanlipoint (ST.36) by	D3 Other device	A1 Same use	P3 different population	R1 High quality	D3 A1 P3 R1
4	Effect of Acupuncture Combined with Blood-letting by a Three-edged Needle on 50 cases of Bell's Palsy at	In this study, A sterilized three-edged needle (middle size) and filiform needles (0.25 mm × 40 mm and 0.25 mm× 25 mm) were used. Acupuncture plus blood-letting can produce good	D3 Other device	A1 Same use	P1 Applicable	R1 High quality	D3 A1 P1 R1
5	Does the effect of acupuncture depend on needling sensation and manipulation?	Acupuncture was performed using stainless steel single-use Disposable Acupuncture needles (0.20 mm×30 mm;DongBang Acupuncture).this study show that needle rotation	D3 Other device	A1 Same use	P1 Applicable	R1 High quality	D3 A1 P1 R1

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6	Prurigo nodularis after acupuncture	In this study ,a case of Prurigo nodularis (PN) after the acupuncture was reported,which indicated that the importance of understanding the possible	D3 Other device	A1 Same use	P1 Applicable	R3 Insufficient information	D3 A1 P1 R3
7	Effect Of Acupressure On Nausea, Vomiting, Anxiety And Pain Among Post-Cesarean Section Women In Taiwan	In this study ,Results indicated that the experimental group had significantly lower anxiety and pain perception of cesarean experiences than the control group.Significant differences were found in all physiologic indices between the two	D3 Other device	A1 Same use	P1 Applicable	R1 High quality	D3 A1 P1 R1
8	Acupuncture point injection therapy plus pharmacotherapy for chronic obstructive pulmonary disease: A systematic review of randomised	Five English and four Chinese databases were searched from inception to May 2015. Results from meta-analyses showed the combination of acupuncture point injection therapy plus pharmacotherapy produced better outcomes	D3 Other device	A1 Same use	P1 Applicable	R1 High quality	D3 A1 P1 R1
9	The Successful Treatment of Pain Associated with Scar Tissue Using Acupuncture	In this case report, a 48-year-old female who had suffered severe scar pain for 3 months was treated with acupuncture using the Wei Ci technique (surrounding the dragon).The patient	D3 Other device	A1 Same use	P1 Applicable	R1 High quality	D3 A1 P1 R1

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10	Abdominal acupuncture treatment of chronic atrophic gastritis of 26	Choosing 0.22 mm x 40 mm Disposable Acupuncture needles, the total effective rate was 84.6%, and suggests that	D3 Other device	A1 Same use	P1 Applicable	R1 High quality	D3 A1 P1 R1
11	Neiguan points breathe in breathe out method to treat hiccups	From May ,2004 to December 2009.Adopting sucked into call back acupuncture treatment of inverse 97 cases ,	D3 Other device	A1 Same use	P1 Applicable	R1 High quality	D3 A1 P1 R1
12	Local injection therapy combined with acupuncture Needle and	205 patients.Using local injections of invigorate the circulation of fluid of anti-inflammatory analgesic, combined with acupuncture,, some cases with needle knife after	D3 Other device	A1 Same use	P1 Applicable	R1 High quality	D3 A1 P1 R1
13	Acupuncture Treatment of Tuberculous Pleurisy Complicated by Clinical Observation	In this study ,though observe the acupuncture treatment of tuberculous pleurisy complicated hiccup effect,Cured 40 cases, effective in 11 cases, 4 cases the total	D3 Other device	A1 Same use	P1 Applicable	R1 High quality	D3 A1 P1 R1

Sutability Criteria	Description	Grading System	
Appropriate device	Were the data generated from the device in question?	D1	Actual device
		D2	Equivalent device
		D3	Other device
Appropriate device application	Was the device used for the same intended use (e.g., methods of deployment, application, etc.)?	A1	Same use
		A2	Minor deviation
		A3	Major deviation
Appropriate patient group	Where the data generated from a patient group that is representative of the intended treatment population e.g., age, sex, etc.) and clinical condition (i.e., disease, including state and severity)?	P1	Applicable
		P2	Limited
		P3	Different population
Acceptable report/data collation	Do the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	R1	High quality
		R2	Minor deficiencies
		R3	Insufficient information

## 4.6 Analysis of the clinical data

Tabulation of clinical analysis of data

Intended Evaluation	Citable Data	Data source	Journal Title	Description
Product performance test	ISO 17218:2014 test report	Suzhou HuaLun Medical	/	The data is from intended evaluating device
Biocompatibility evaluation	Biocompatibility test report	School of nuclear medicine,	/	The data is from intended evaluating device
Evaluation of Residual risk and	Risk management report	Suzhou HuaLun Medical Appliance	/	The data is from intended evaluating device
Evaluation of both safety and	Post-market product quality follow report	Suzhou HuaLun Medical Appliance	/	The data is from intended evaluating device

1	Nausea Control by Needling at Acupuncture Point Neiguan (PC6) During an Intraoral Impr	ScienceDirect	Journal of Acupuncture and Meridian Studies	The device in the data form the proposed evaluating device, with the same intended use, product structure, operation principle and performance parameters. The data indicates that the
2	Cluster headache in an elderly patient treated with neurofunctional acupuncture a case report	ScienceDirect	Acupuncture and Related Therapies	The device in the data form the proposed evaluating device, with the same intended use, product structure, operation principle and performance parameters, the data show that acupuncture can bring
3	Effect of Zusanli (ST.36) Electroacupuncture at Two Frequencies on the Bioavailability of <sup>99m</sup> Tc-Sodium	ScienceDirect	Journal of Acupuncture and Meridian Studies	The device in the data form the proposed evaluating device, with the same intended use, product structure, operation principle and performance parameters, the data show that the proposed evaluating device is safe and effective.
4	Effect of Acupuncture Combined with Blood-letting by a Three-edged Needle on 50 cases of	ScienceDirect	Journal of Traditional Chinese Medicine	The device in the data equal to the proposed evaluating device with the same intended use, operation principle and performance parameters, The data indicates that the

Evaluation of Applicability and Clinical application	5	Does the effect of acupuncture depend on needling sensation and	ScienceDirect	Complementary Therapies in Medicine	The device in the data equal to the proposed evaluating device with the same intended use, operation principle and performance
	6	Prurigo nodularis after acupuncture	ScienceDirect	JAAD Case Reports	The device in the data equal to the proposed evaluating device with the same intended use, operation principle, The data indicates that after using the proposed device
	7	Effect Of Acupressure On Nausea, Vomiting, Anxiety And Pain Among Post-Cesarean SectionWom	ScienceDirect	The Kaohsiung Journal of Medical Sciences	The device in the data equal to the proposed evaluating device with the same intended use, operation principle and performance parameters. The data indicates that the proposed device is safe
	8	Acupuncture point injection therapy plus pharmacotherapy for chronic obstructive pulmonary disease: A systematic	ScienceDirect	European Journal of Integrative Medicine	The device in the data equal to the proposed evaluating device with the same intended use, operation principle, The data indicates that the proposed device is safe and effectivefor stable COPD
	9	The Successful Treatment of Pain Associated with Scar Tissue Using	ScienceDirect	Journal of Acupuncture and Meridian Studies	The device in the data equal to the proposed evaluating device with the same intended use, operation principle, The data indicates that the

10	Abdominal acupuncture treatment of chronic atrophic gastritis of 26 cases	CNKI	Journal of Guangxi College of T.c.m	The device in the data equal to the proposed evaluating device with the same intended use, operation principle and performance parameters, the data
11	Neiguan points breathe in breathe out method to treat hiccups	CNKI	Chinese acupuncture and moxibustion	The device in the data equal to the proposed evaluating device with the same intended use, operation principle, the data indicates that the
12	Local injection therapy combined with acupuncture Needle and acupuncture	CNKI	Journal Of Practical Traditional Chinese Internal Medicine	The device in the data equal to the proposed evaluating device with the same intended use, operation principle, the data indicates that the proposed device is safe
13	Acupuncture Treatment of Tuberculous Pleurisy Complicated by Clinical Observation of 55 Cases	CNKI	Journal Of Practical Traditional Chinese Internal Medicine	The device in the data equal to the proposed evaluating device with the same intended use, operation principle, the data indicates that the proposed device is safe and effective for treating



#### **4.6.1 Requirement on safety (MDD ER1/AIMDD ER1)**

Performance safety and Biocompatibility are meet relevant international standard. The test results show that it is safety.

The safety of device had passed verification by the ISO 17218:2014 test reports, and we have complete the Biological compatibility evaluation report. So the material which contact with patient is safety. The quality assurance system had got the certification that compliance with the requirement of ISO13485, which ensure that the development and manufacture activities are under control and trustable.

#### **4.6.2 Requirement on acceptable benefit/risk profile (MDD ER1/AIMDD ER1)**

According to the EU coordination standard EN 14971, we establish risk management plan, and identify risk, evaluate risk, analysis risk, control risk, and then take control measure to reduce risk to up to acceptable criterion.

From 2012 to now, in domestic and Europe, Asia and other countries, never received a customer because of the physical and chemical indicators of our products is unqualified, the pyrogen test is unqualified complaints, such as has not occurred against the background of medical accident customer complaints.

Product Risk of product:

- 1、 The use of non specialist acupuncturist can lead to medical malpractice.
- 2、 The small seal of the needle will cause bacterial infection.
- 3、 When using broken needle.
- 4、 Acupuncture needle tip damage, damage the skin when pulling out.
- 5、 The connection between the needle and the needle handle is not firm enough, needle body is separated from the handle of the needle.

The above risks can be through the quality inspection of product to reduce risk to a minimum, can be controlled.

Product Benefit of product:

1、 Piercing the skin used in acupuncture treatment, get the expected purpose acupuncture treatment.

So the product benefits outweigh the risks.

#### **4.6.3 Requirement on Performance (MDD ER3/AIMDD ER2)**

Our company according to the product's intended use and intended use to the physical and chemical properties, set the performance requirements of the product:

1、 Needle hardness:  $\geq 460$  HV0.2kg

2、 Needle toughness: The needles of Disposable Acupuncture needles should have good toughness, and there should be no cracks, breaks and delamination after the winding test.

3、 Corrosion resistance: The needle should have good corrosion resistance.

4、 Sharpness of needle: The needle 0.4 N top pressure and contact pressure on the top of the lump, puncture stress is less than or equal to 0.7 N.

5、 Connection firmness: The needle body and the needle handle should be firmly connected, value under pull-out test at 9 N, two axial displacement shall not be greater than 3mm.

6、 Needle appearance: The tip of the needle should be round, not biased, without burrs, bending, hook and other defects.

7、 Surface roughness: The needle body surface should be smooth, with no obvious scar, scar and thread defects such as surface roughness Ra value is less than or equal to 0.63um

8、 Pin winding filament: The spiral ring of the needle handle should be arranged evenly without obvious distance.

9、 Handle color: The surface of the needle handle should be uniform in color and luster. If the handle is silver plated, the coating shall be silver white and shall not have any coating.

10、 Shank burr: The handle of acupuncture needle must not be burr.

11、 Curvature: Disposable Acupuncture needles should be straight and must not have obvious bends.

12、 Sterile: The products should be sterile

#### **4.6.4 Requirement on acceptability of side-effects (MDD ER6/AIMDD ER5)**

As with any treatment, acupuncture does pose some risks, but the frequency of adverse effects is low when administered by a licensed and properly trained practitioner using sterile needles.

Possible side effects can include nausea, dizziness, fainting, and soreness, minor bleeding, or bruising at the needle sites.

Improperly administered acupuncture can cause serious adverse effects, such as infections, nerve and blood vessel damage, needle breakage, and punctured organs. Punctured pleural membranes around the lungs can lead to collapsed lungs. People with a rare, anatomical variation known as sternal foramen (a hole in the breastbone) are at risk of lung or heart (pericardium) puncture.

There have been some reports of needles being left in after the treatment. A report published in the *Bulletin of the World Health Organization* summarized the acupuncture-related adverse effects in Chinese language studies.

Acupuncture may not be right for people with certain health conditions. The risk of bleeding or bruising increases if you have a bleeding disorder or are taking blood thinners, such as warfarin (Coumadin).

Acupuncture shouldn't be used in place of standard care. Avoiding or delaying standard care may have serious consequences.

## 5. Conclusions

Analysis of the contribution of literatures, post-market product quality follow and similar products comparison results show that the Disposable Acupuncture needles are consistent with the proposed evaluating device in intended use, specification and parameters. Besides, the safety and performance of the proposed evaluating device also meet the requirements of clinical research literature and performance requirement, the identified risks in Risk management document be solved in the clinic as well. All the above proved the proposed evaluating device is safe and effective.

For each proposed clinical indication state:

- the clinical evidence demonstrates conformity with relevant Essential Requirements;
- the performance and safety of the device as claimed have been established; and
- the risks associated with the use of the device are acceptable when weighed against the benefits to the patient.

## 6. Data of the next clinical evaluation

The products of our company, there is no significant risk in the market sales of more than 10 years, no adverse events, the use of security and stability. So after I listed company product quality tracking report is updated once every five years.

## 7. Dates and signatures

Date of the clinical evaluation report: 26 of December 2017

Date and Signature of Evaluators Signature: 倪承浩2017.12.26

Statement: Agree to report content.

Date and Signature of Final release by the manufacturer: 余瑞兴 2017.12.26

## 8. Qualification of the responsible evaluators

The author who drafted this report is Yu Suqiong, and the CV of the team of Clinical

evaluation refers to the following table.

Suzhou HuaLun Medical Appliance Co., Ltd.

Version: B/6

CE TCF

Effective date: 2017.12.26

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9. References

- 1、 Nausea Control by Needling at AcupuncturePoint Neiguan (PC6) During an IntraoralImpression-Taking Procedure
- 2、 Cluster headache in an elderly patient treated with neurofunctional acupuncture a case report
- 3、 Effect of Zusanli (ST.36) Electroacupuncture atTwo Frequencies on the Bioavailability of<sup>99m</sup>Tc-Sodium Pertechnetate and onLabeling of Blood Constituents in Rats
- 4、 Effect of Acupuncture Combined with Blood-letting by a Three-edgedNeedle on 50 cases of Bell’s Palsy at the Acute Stage
- 5、 Does the effect of acupuncture depend on needlingsensation and manipulation?
- 6、 Prurigo nodularis after acupuncture
- 7、 Effect Of Acupressure On Nausea, Vomiting,Anxiety And Pain Among Post-Cesarean SectionWomen In Taiwan
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