河南核信恒达实业有限公司

HENAN HEXIN HENGDA INDUSTRIAL CO., LTD.

CE Technical Files
Of Heat Pads

Author: Zhang Jun

Approval: Wang Zhili

File number: CE-01

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Technical Files	File Number:CE-01-00
	Revision: A/0
	Chapter: 00
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临床调查（MDD 93/42/EEC附录十）

11.Manufacture Environment control 生产环境控制

12.Vigilance System 警戒系统程序

Manufacturer: Henan Hexin Hengda Industrial Co., Ltd.

Registration Address: East Lake Hengda Industrial park Shihe District 464000

Xinyang City,Henan China

Business Address: East Lake Hengda Industrial park Shihe District 464000

Xinyang City,Henan China

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See attachment

Henan Hexin Hengda Industrial Co., Ltd.

File No: CE-TCF-002

CE

EC Declaration of Conformity

CE

Regarding Medical Device Directive (93/42/EEC)

Manufacturer

Name: Henan Hexin Hengda Industrial Co., Ltd.

Address:East Lake Hengda Industrial park Shihe District 464000 Xinyang City,Henan China

Product

Name：single use heating pads

Type：N/A

Classification：IIa

We confirm our product can meet the requirement of Medical Device Directive 93/42/EEC including 2007/47/EC and ISO 9001.

The medical device has been assigned to class IIa according to Annex V of the Directive 93/42/EEC.

The product concerned has been manufactured under a quality management system according to Annex V of Directive 93/42/EEC.

Signature:

Date: 09.01.2018

Add: East Lake Hengda Industrial park Shihe District 464000 Xinyang City,Henan China

Tel: 86-371-60222092 Fax:86-371-60222092

3.1 产品说明 Product Description:

此暖贴可用于热疗、取暖等用途。The heat pads can be used for body warmer, heating, and thermal therapy.
暖贴旨在迅速的提供热量以帮助促进治疗和康复。这个便携式的暖贴可随时随地使用，而且不需要电加热。
此暖贴极易激活使用，只需将产品拆封即可激活使用，是市场上最容易激活使用的产品之一。
此暖贴一次性使用。根据产品设计，产品贴于内衣上使用，部分产品可直接贴于皮肤上使用。
The heat pad is to quickly provide heat to help promote the treatment and rehabilitation. This portable warm pad can be used anywhere, anytime, and don't need electric heating. It is air-activated and easily to use, once open the bag it is activated and can be used.
The heat pad is one-time use, as per product design adhesive the pad on underwear, some pad can be directly adhesive to skin.

3.2 采用标准 Standards:

企业标准Company Standards：QB/ BANGJI-001-2012
相关协调标准Applied Standards：
EN ISO 15223-1-2012医疗器械.用于医疗器械标签、作标记和提供信息的符号.通用要求
EN ISO 15223-1-2012Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied
EN ISO 14971:2012医疗器械 风险管理的应用
EN ISO 14971:2012Medical devices - Application of risk management to medical devices (ISO 14971:2012)
EN ISO 13485:2012医疗设备.质量管理体系.管理要求
EN ISO 13485:2012Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2012) EN ISO 13485:2012/AC:2012
EN ISO 14155-1:2011以人为对象的医疗器械的临床调查--良好临床规程
EN ISO 14155-1:2011Clinical investigation of medical devices for human subjects - Part 1: General requirements (ISO 14155-1:2003)
ISO10993-5:2009医疗器械的生物学评价--第5部分：体外细胞毒性试验
ISO10993-5:2009Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010医疗器械的生物学评价--第10部分：刺激和皮肤敏化试验
ISO 10993-10:2010Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

3.3 主要参数 Main Parameters:

3.3.1组成Components

铁粉、蛭石粉、活性炭、盐
Iron powder, Vermiculite, activated carbon, salt

3.3.2 颜色Color

3.3.2.1 铁粉Iron Powder——银灰色silver gray

3.3.2.2　蛭石粉Vermiculite——金黄色Golden Yellow
3.3.2.3活性炭Activated carbon——黑灰色black gray
3.3.2.4盐Salt——白色或微黄或青白色White or light yellow or bluish white
3.3.3气味Odor
3.3.3.1铁粉Iron powder——无味no smell
3.3.3.2蛭石粉Vermiculite——无味no smell
3.3.3.3活性炭Activated carbon——无味no smell
3.3.3.4 盐 Salt ——无味 no smell
3.3.4外观Appearance
3.3.4.1 铁粉 Iron powder——粉状 powder
3.3.4.2 蛭石粉 Vermiculite——粉状 powder
3.3.4.3 活性炭 Activated carbon——粉状 powder
3.3.4.4 盐 Salt——粉状或晶体 powder or crystal
3.3.5温度规格Temperature
在常温下激活使用，表面温度为 35° C -65° C
Activated in normal temperature, surface temperature 35° C -65° C
3.3.6 封烫质量 Seal Quality
放置 12 小时不发热
3.3.7产品尺寸Product Size

尺寸Size：10cm x 20cm	weight：55 g/pcs	包装Packing：1 pcs/ bag
尺寸Size：10cm x 13cm	weight：45g/pcs	包装Packing：1pcs/ bag
尺寸Size：9.5cm x 13cm	weight：45g/pcs	包装Packing：1pcs/ bag
尺寸Size:10cm x 8cm	weight：30g/pcs	包装Packing：1pcs/ bag
尺寸Size：10cm x 7cm	weight：30g/pcs	包装Packing：1pcs/ bag
尺寸Size：7cm x 9cm	weight：17g/pcs	包装Packing：1pcs or 2pcs/ bag
尺寸Size：9.2cm x 5.5cm	weight：30g/pcs	包装Packing：1pcs or 2pcs/ bag

备注Remarks：其他尺寸以客户设计要求The other sizes as per customers' requested.
3.3.8每个产品的重量The weight for heat pad
由客户设计 As per customer's design
3.3.9外袋材质Inner packing bag material
镀铝塑料袋 Aluminium foilbag
备注：由客户定义 or customized as per customer request
3.3.10外袋厚度 Outer packing bag material
以客户设计要求 As per customer's request
3.3.11彩盒尺寸（如果有）packing box size
以客户设计要求 as per customer's request
3.3.12彩盒材质（如果有）packing box material
以客户设计要求as per customer's request

3.3.13每箱数量qty/per CTN

10袋/PP袋，300袋/箱　10bags/transparency PP bags, 300bags/CTN

备注：以客户设计要求 OR as per customer’s request

3.3.14包装方式Packing Method

按照客户要求数量装箱，瓦楞纸箱，标签或唛头印（贴）在外箱上

The qty in each CTN as per customer’s request, label or sidemark should be printed in cartons.

3.3.15标识及产品说明书Identification and Product Instruction

3.3.15.1包装袋上应有下列标识：The packing bag should include below information

a) 产品名称；product name
b) 产品规格；product size
c) 产品批号 （含制造日期）；production lot number(include manufacturing date)
d) 制造商；manufacturer
e) 欧盟授权代表名称和地址；EU Rep name and address
f) 批号的符号和批号数码；Lot label and Lot no.
g) 不得重复使用的符号；label “DO NOT REUSE”
h) 产品系列号的字样；Product serial number
i) 顾客特殊要求等信息；customers special request information
j) 请看说明书符号；label for “USER MANUAL”
k) CE标志等信息；label for “EC REP”
l) 产品警示；label for “ALERT”

3.3.15.2包装箱标签应有下列标志：The packing carton should include below information

a) 收货客户名称；Consignee name
b) 收货地址；address
c) 包装数量；packing qty
d) 本箱序号和总箱数；the serial No. of the CTN and total CTN no.
e) 产地标识；Certificate of Origin
a) 产品名称；Product Name
b) 产品型号；Product Model
c) 产品规格；Product Size
d) 产品数量；Products Qty
e) 产品批号；Lot No.
f) 制造日期；Manufacturing date
g) 产品防护信息、防护标志；Product Protection information and label

备注：凡认为对于装运货物没有必要的元素中的任何一个可予以省略。If the label no need or necessary during packing and shipment, please ignore it.

3.3.15.3使用说明书应有下列内容User Manual should include below information

a) 产品用途；product indications
b) 产品使用说明 product directions

c) 产品注意事项Cautions

d) 产品储存方法Storage

3.3.16产品批号Lot#

Lot # CNYYMMXXXXX

具体为:

CN - 中国

YY - 年份的后两个数字

MM - 月份

XXXXX 本月批号的流水号

例如: 2011 年 06 月第 8 批的的批号为 LOT# CN140600008 。

3.3.17包装箱批号 CTN Lot#

在标签上，和产品上的批号一致 Keep the same Lot# for ctn and bag, box etc

3.3.18包装箱尺寸 CTN Size

根据客户要求的数量和客户设计的产品尺寸（或彩盒尺寸）设计 As per customer’s order qty and box design size

3.3.19生物相容性 biocompatibility

接触皮肤产品的包装袋应确保符合 EN ISO 10993.1：2009第1部分：评价与试验

The materials directly to skin must comply to standards EN ISO 10993.1：2009 part 1:Assess and Test

4.1 产品定义及分类 6.1definition and classification of products

根据上述预期用途，根据 MDD93/42/EEC 附录 IX 之分类准则，对产品进行定义和分类。

The products is defined and classified according to the classification criterion of MDD93/42/EEC appendix IX and intended function.

4.1.1 产品定义 definition of products

有源医疗器械定义：任何不是依靠人体或重力直接产生的，而是依靠电能源或其他动力源工作的以及通过转换这种能量而产生作用的医疗器械。用于在有源医疗器械和患者之间传递能量、物质或其他元素而本身不发生重大变化的医疗器械不属于有源医疗器械。有源医疗器械是依靠电能或者其他形式能源才能发挥作用和产生效果的医疗器械。能源的种类有电能、核能、化学能、太阳能、电热能等。有源医疗器械指依靠上述一种或几种能源发挥其功能的。

Definition of active medical devices: any medical devices work relying on power or other power producer to transfer energy rather than rely on gravity and labor.those medical devices used to do transfer of energy,substance,and other elements between medical devices and patients do not belong to active medical devices.active medical devices can only function relying on power and other energy resources.these resources includes electrical energy, nuclear energy, chemical energy, solar energy,electric heating etc.active medical devices works relying on one or several kinds of resources mentioned above.

根据预期用途及附录 IX 的定义，暖贴属于：according to the definition of intended function and the appendix IX, warmer pad belongs to :

a) 属有源医疗器械（化学能）；A):active medical device

b) 属非侵入式医疗器械；b)：non-invasive medical device

4.1.2 产品主要成分 6.1.2 main ingredients

铁粉、蛭石粉、活性炭、盐 iron powder, vermiculite powder,activated carbon, salt

4.1.3 产品工作原理 6.1.3 operating principle of product

暖贴的反应原理为利用原电池加快氧化反应速度，将化学能转变为热能

The reaction principle of warmer pad: accelerating oxidation by galvanic cell so that chemical energy be transferred to heat energy.

负极 negative pole ： Fe-2e-=Fe2+

正极 positive pole：O2 + 2H2O + 4e-=4OH-

总反应 overall reaction：2Fe + O2 + 2H2O=2Fe(OH)2

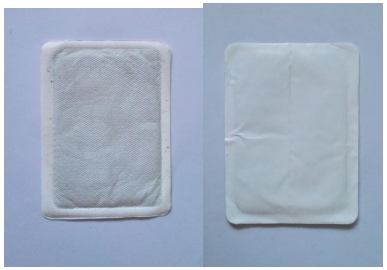
4Fe(OH)2 + 2H2O + O2=4Fe(OH)3↓2Fe(OH)3 ==== Fe2O3+3H2O

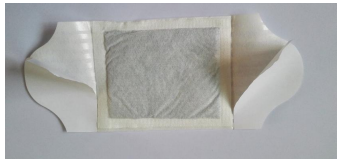
4.1.4 产品分类 6.1.4 classification of products

根据 MDD93/42/EEC 附录 IX 之分类准则，暖贴是非侵入式有源医疗器械，符合分类规则中原则 9 的规定（用于控制或交换能量的所有有源医疗器械，应为第 IIa 类），故暖贴属于 IIa 类。

according to the definition of intended function and the appendix IX, warmer pad belongs to non-invasive medical device. As it conforms to the 9th rule in the classification rules(all active medical devices used to control or transfer energy should belong to the IIa), warmer pad belong to IIa.

Technical Files（part A）	File Number 文件编号：CE-01-05
	Revision 版本: A/0
	Chapter 章节:05
Product Critical Characteristic Parameter 产品关键特性参数	Page code 页码: 1/2

编号 Item	名称 Product Name	图片 Product Picture	尺寸 cm Size	包装 Packing	表面温度 Surface Temperature	使用温度(贴于内衣或用毛巾裹住后测试) Using Temperature(adhesive on the underwear or skin, or test wrapped with towel)	发热时间 Heating time
HD001W	暖宝宝 Body warmer pad		10x13 9.5x13	1 片一袋 1pcs/per bag	35-68℃	35-45℃	10 小时 10 hours
HD002W	迷你暖贴 Mini warmer patch		10x7	1 片一袋 1pcs/per bag	35-65℃	35-45℃	8 小时 8 hours

HD003W	暖足贴 Toe warmer		9X7	1 片一袋或 2 片一袋 1pcs/per bag, 2pcs/per bag	35-58℃	35-45℃	6-8 小时 6-8 hours
HD004W	暖手袋 Hand warmer		9.2x5.5	1 片一袋或 2 片一袋 1pcs/per bag, 2pcs/per bag	35-58℃	35-45℃	6-8 小时 6-8 hours
HD005W	八字暖宫贴 Menstrual Cramp Relief Patch		20x10	1 片一袋 1pcs/per bag	35-68℃	35-45℃	12 小时 12 hours
HD006W	亲肤理疗贴 Physical therapy patch		10x8	1 片一袋 1pcs/per bag	35-50℃	35-40℃	6-8 小时 6-8 hours

06.1Product Composition List 产品组件清单

06.2Labeling and Language 标签和语言

06.3Users manual, instruction for Use 产品说明书

06.4 Work Flow 生产流程图

06.5 Packaging 包装要求

6.1 暖贴的组件清单如下：

Product Compositions List:

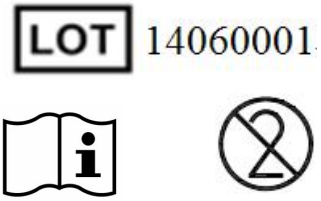
序号 Item	供方名称 Suppliers' Name	类别 Class	地址 Address
1	背胶纸 Adhesive paper	A 类 Class A	义乌市佐罗胶粘制品有限公司 Yiwu Zuoluo Adhesive Paper Co., Ltd.
2	无纺布 No-woven Cloth	A 类 Class A	山东华业无纺布有限公司 Shandong Huaye Non-wovens Co., Ltd.
3	活性炭 activated charcoal	A 类 Class A	巩义市鹏兴净水材料有限公司 Gongyi Pengxing Jingshui Cailiao Co., Ltd.
4	铁粉 Iron Powder	A 类 Class A	巩义市桥沟金鑫粉末冶金厂 Gongyi Qiaogou Jinxin Fenmo Zhiye Factory
5	吸水树脂 Absorbent Polymers	A 类 Class A	济南华迪工贸有限公司 Jinan Huadi Gongmao Co., Ltd.
6	蛭石粉 Vermiculite Powder	A 类 Class A	灵寿县达利通矿产制品厂 Lingshou Dalitong Kuangchan Zhipin Factory
7	包装袋 Packing Bag	A 类 Class A	郑州兴中塑料彩印有限公司 Zhengzhou Xingzhong Plastic Printing Co., Ltd.
8	不干胶 Adhesive Sticker	A 类 Class A	苍南蒙其克不干胶有限公司 Cangnan Mengqike Buganjiao Youxian Gongsi
9	盒子，展示盒，标签 Packing box, Display box, Label	B 类 Class B	郑州金悦包装设计有限公司 Zhengzhou Jinyue Baozhuang Sheji Co., Ltd.
10	纸箱，卡纸 Carton, Paperboard	C 类 Class C	淮阳县宏图包装纸制品有限公司 Huaiyang Hongtu Baozhuangzhi Zhipin Co., Ltd.

Labeling:

CE 0197	HEAT PADS	HEXIN 核信	
	MODEL NAME	10x13cm	
Temperature Range	35-68℃	Use Time	12 hours

2005-09-15

2004-06



(1)Do not apply Body warmers directly to the skin,but on the underwear, heat may causes burns.
(2)Supervision is needed for use with the elderly, infants, children, people with sensitive skin, and for people not fully aware to the sensation of heat.
(3)People with diabetes, frostbite, scars, open wounds, or circulatory problems should consult a physician before using Body warmers.
(4)Do not open cloth pouch. Do not allow the contents to come in contact with eyes or mouth, If such contact occurs, wash thoroughly with clean water.
(5)Do not use in oxygen-enriched environments.
(6)For external use only, check skin regularly and remove pack immediately if it becomes uncomfortable hot.
(7)Do not use when sleeping.

Henan Hexin Hengda Industrial Co., Ltd.
Tel : 0371-60222092 FAX: 0371-60222092
Registration Address:East Lake Hengda Industrial park Shihe District 464000 Xinyang City,Henan China

EC REP

Company Name：SUNGO Certification Company Limited
Add:1 Four Seasons Terrace West Drayton, Middlesex London, UB79GG, United Kingdom
Tel: +44 20 75868010

Language Requirements for Labeling in the EU Member states

Country \ Language	Danish	Dutch	English	Finnish	French	German	Greek	Icelandic	Italian	Norwegian	Portuguese	Spanish	Swedish	Czech	Estonian	Russian	Hungarian	Latvian	Lithuanian	Polish	Slovakian	Slovenian
Austria						★																
Belgium		★			★	★																
Denmark	★																					
Finland				★									★									
France					★																	
German						★																
Greece							★															
Holland		★																				
Iceland								★														
Ireland			★																			
Italy									★													
Luxemburg					★	★																
Norway										★												
Portugal											★											
Spain												★										
Sweden													★									
Switzerland					★	★																
England			★																			
Cyprus							★															
Czech														★								
Estonia			★												★	★						
Latvia			★													★		★				
Lithuania																			★			
Malta			★																			
Poland																				★		
Slovakia																					★	
Slovenia																						★
Hungry																	★					

Heat pads

1.OVERVIEW

Product Name: Body Warmer Pad
Size: 10*13cm
Net Weight:45g/pc
Average temperature:53℃
Max temperature :68℃
Duration time: 10hours
Do not apply it directly to the skin,but on the underwear

Product Name: Mini warmer patch
Size: 10*7cm
Net Weight:30g/pc
Average temperature:53℃
Max temperature :65℃
Duration time: 8hours
Do not apply it directly to the skin,but on the underwear

Product Name: Toe Warmer
Size:7*9cm
Net Weight:17g/pc
Average temperature:42℃
Max temperature :58℃
Duration time: 6-8hours
Do not apply it directly to the skin,but on the underwear

Product Name: Hand Warmer
Size:9.2*5.5cm
Net Weight:30g/pc
Average temperature:42℃
Max temperature :58℃
Duration time: 6-8hours
Put into gloves and pockets

Product Name: Menstrual Cramp Relief Patch
Size:10*20cm
Net Weight:55g/pc
Average temperature:53℃
Max temperature :68℃
Duration time: 12hours
Do not apply it directly to the skin,but on the underwear

Product Name: Physical therapy warmer patch
Size:10*8cm
Net Weight:30g/pc
Average temperature:45℃
Max temperature :50℃
Duration time: 6-8hours
Apply it directly to the skin, it is therapy warmer to relieve pains

ALL ABOVE
Intended use: This product is used to compress or heating

Active Ingredients: Iron powder, Vermiculite, activated carbon, water and salt

USAGE: Can be used by athletes, outdorr enthusiasts, sportsmen, skiers, construction workers-anyone who hates cold weather

Indications: Mainly to keep parts of body warm in winter, and relieving the pains from rheumatic, stiff neck and shoulder, backaches, muscular fatigues, arthritis, waist, and other diseases because of cold weather.

2.Specifications

name	Body Warmer pad/mini warmer patch/toe warmer/hand warmer/menstrual cramp relief patch/physical therapy warmer patch
Ingredients	Iron powder, Activated carbon, Vermiculite, Water and Salt.
Characteristics	1.easy to use, no odor, no microwave radiation, no stimulus to skin 2.natural ingredients, safe and environment friendly 3.heating simple, no need outside energy, No batteries, no microwaves, no fuels 4. Multi Function, relax the muscles and stimulate the blood circulation 5.suitable for indoor and outdoor sports
How to use	1.Open the pouch, tear off the safeguard paper and stick the pad onto your underwear, Or sticking on the skin directly. 2.Please remove the pouch slowly after use in order to avoid the damage to the clothes.

Storage	Keep in dry, cool place and avoid exposure to sunlight.
Time of validity	3 years
Addition	We can provide OEM according to your detail requirement.

3.Features

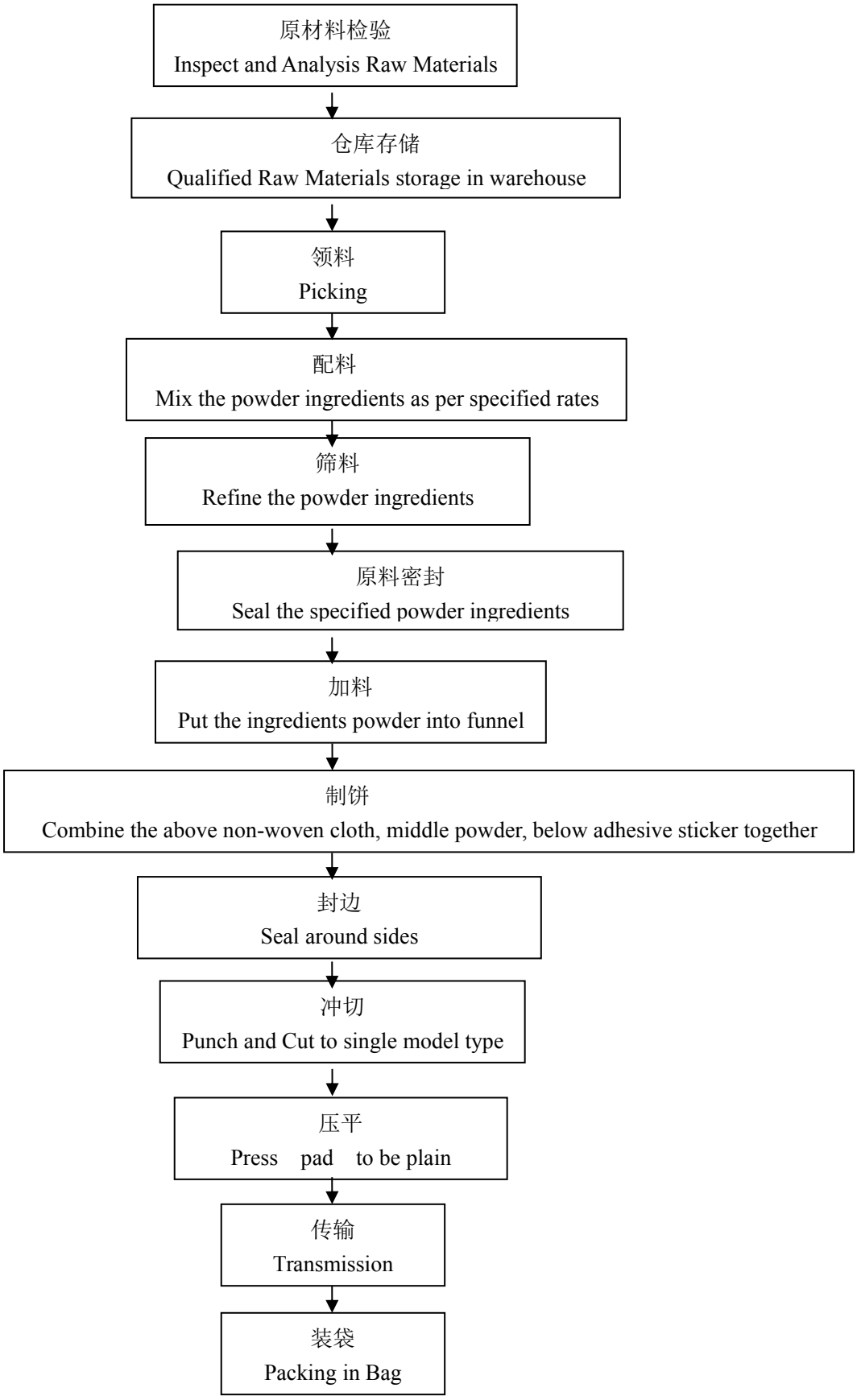
- Natural ingredients, no side effect
- Air-activated heating
- Long lasting& effective
- It offer warm security to all kinds of crowd
- Relive pains on your body from the cold

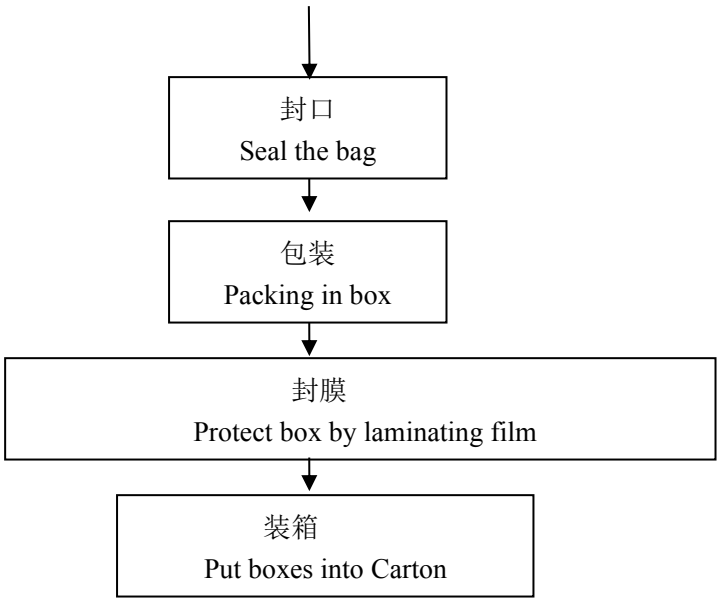
Warning (for 10*13cm Body Warmer Pad, 10*7cm mini warmer patch, 10*20cm Menstrual Cramp Relief Patch, 7*9cm Toe Warmer, 9.2*5.5cm hand warmer)

1. Do not apply this warmer product directly to the skin,but on the underwear, heat may causes burns.
2. Supervision is needed for use with the elderly, infants, children, people with sensitive skin, and for people not fully aware to the sensation of heat.
3. People with diabetes, frostbite, scars, open wounds, or circulatory problems should consult a physician before using Body warmers.
4. Do not open cloth pouch. Do not allow the contents to come in contact with eyes or mouth, If such contact occurs, wash thoroughly with clean water.
5.Do not use in oxygen-enriched environments.
6.For external use only, check skin regularly and remove pack immediately if it becomes uncomfortable hot.
7.Do not use when sleeping.

Warning (for 10*18cm physical therapy warmer patch)

1. This warmer product with therapy effective, please put it directly to the skin.
2. Supervision is needed for use with the elderly, infants, children, people with sensitive skin, and for people not fully aware to the sensation of heat.
3. People with diabetes, frostbite, scars, open wounds, or circulatory problems should consult a physician before using Body warmers.
4. Do not open cloth pouch. Do not allow the contents to come in contact with eyes or mouth, If such contact occurs, wash thoroughly with clean water.
5.Do not use in oxygen-enriched environments.
8.For external use only, check skin regularly and remove pack immediately if it becomes uncomfortable hot.
9.Do not use when sleeping.


原材料检验
Inspect and Analysis Raw Materials
仓库存储
Qualified Raw Materials storage in warehouse
领料
Picking
配料
Mix the powder ingredients as per specified rates
筛料
Refine the powder ingredients
原料密封
Seal the specified powder ingredients
加料
Put the ingredients powder into funnel
制饼
Combine the above non-woven cloth, middle powder, below adhesive sticker together
封边
Seal around sides
冲切
Punch and Cut to single model type
压平
Press pad to be plain
传输
Transmission
装袋
Packing in Bag


封口
Seal the bag
包装
Packing in box
封膜
Protect box by laminating film
装箱
Put boxes into Carton

1、包装原材料：郑州兴中塑料彩印有限公司检验报告见附件

packing raw material:zhengzhou Xingzhong plastic printing Co., Ltd. Inspection report please see the attachment.

2、如果更换包装材料供方，需重新对供方进行确认。If changing the packing supplier, we need to test the suppler again

3、对合格供方提供的包装材料进行检验和验证，符合检验规范的要求。Making a test and determination for the packing supplied by the qualified supplier according to the material inspection standard

4、外包装采用五层瓦楞纸纸箱，内有中包装，运输方式按照客户要求，一般为汽车运输。产品不存在精密零配件，运输过程中的震动，不会对产品的质量造成影响。The outer packing is five-layer corrugated fiberboard carton, it includes middle package. The ways of transportation meet for the customer requirements, generally speaking, it will be truck. there are no sophisticated fittings. The jounce will not affect the quality when in transportation.

5、包装件和流通系统 Package and Circulation System

由硬板纸组成的包装件，38*34*20cm 。Package formed by cardboard:38*34*20cm

流通系统为在暖温带气候条件下经由公路运输到达港口后经由海运后经由公路到达目的地。

Circulation System is to transfer, under the warm temperate climate, through road transportation to port, then through ocean transportation to destination.

包装件由制造厂装到托盘上形成单元载荷。以后单元载荷又拆散成单个包装公路运抵目的地。

危害和试验要求

Package unit is loaded in pallet by manufacturer to form unit load. Then unit load is unpicked into unit package to be transported to destination.

Hazard and experiment requirements

流通系统的环节 stage of Circulation System	有关的危害 relevant hazard		涉及试验 involved experiments		试验强度基本值 Basic value of test strength	修正因素 Revising factor	最终试验强度值 Final strength of test
	mechanical 机械的	气候条件 climate	机械的 mechanical	试验前的调节处理或需要的气候试验 regulation before experiment or climate test			
用人工将包装件装在托盘上 Load package in pallet by labor	垂直冲击 Vertical impact	暖温带 warm temperate zone	-	-	-	-	-
将托盘单元载荷运到仓库 Transport loaded pallet unit to warehouse	振动 vibration	暖温带 warm temperate zone	-	-	-	-	-
仓库中贮存单元载荷（放在托盘架上） store unit load in warehouse(put on pallet frame)	堆码 stacking	暖温带 warm temperate zone	堆码 stacking	-	堆码高度：3.0m Height of stacking:3.0m 堆码持续时间：1d Time of stacking:1d	托盘架 pallet frame	堆码高度：3.0m Height of stacking:3.0m 堆码持续时间：1d Time of stacking:1d
将托盘单元载荷由仓库运到运 Transport loaded pallet unit from warehouse to transport cart 输车辆上	振动 vibration	暖温带 warm temperate zone	-	-	-	-	-
用带篷汽车将包装件经公路	振动	暖温带	振动	-	堆码高度：3.0m	托盘承载单元	堆码高度：3.0m

运到码头（距离 50km） Transfer package through road to wharf(distance 50km	vibration	warm temperate zone	vibration		Height of stacking:3.0m 振动持续时间：20min Time of vibration:20min	Pallet loaded unit	Height of stacking:3.0m 振动持续时间：20min Time of vibration:20min
	stacking 堆码		堆码 stacking	-	堆码高度：3.0m Height of stacking:3.0m 堆码持续时间：1d Time of stacking:1d		堆码高度：3.0m Height of stacking:3.0m 堆码持续时间：1d Time of stacking:1d
	水平冲击 Horizontal impact		水平冲击 Horizontal impact	-	速度 1.5m/s Speed:1.5m/s		速度 1.5m/s Speed:1.5m/s
在码头卸包装件 Unload package on wharf	垂直冲击 Vertical impact	暖温带 warm temperate zone	垂直冲击 Vertical impact	-	跌落高度 300mm Drop height:300mm	包装件质量尺寸可装卸性 Package quality dimensions can be loading and unloading	跌落高度 300mm Drop height:300mm
在海港仓库内贮存 store in seaport warehouse	堆码	暖温带 warm temperate zone	堆码 stacking	-	堆码高度：3.0m Height of stacking:3.0m 堆码持续时间：7d Time of stacking:7d	海港仓库 seaport warehouse	堆码高度：3.0m Height of stacking:3.0m 堆码持续时间：7d Time of stacking:7d
将包装件装到船上	水平冲击	暖温带	水平冲击	-	-	-	-

Load package on ship	Horizontal impact	warm temperate zone	Horizontal impact				
	垂直冲击 Vertical impact		垂直冲击 Vertical impact	-	跌落高度 300mm Drop height:300mm	包装件质量尺寸可装卸性 Package quality dimensions can be loading and unloading	跌落高度 300mm Drop height:300mm
海洋运输（距离 7000km） Sea transportation(distance:7000km)	振动 vibration	暖温带 warm temperate zone	振动 vibration	-	堆码高度：3.0m Height of stacking:3.0m 振动持续时间：60min Time of vibration :60min	跨海洋长距离运输 Tran-ocean long distance transportation	堆码高度：3.0m Height of stacking:3.0m 振动持续时间：60min Time of vibration :60min
	堆码 stacking		堆码 stacking	-	堆码高度：3.0m Height of stacking:3.0m 堆码持续时间：7d Time of stacking:7d		堆码高度：3.0m Height of stacking:3.0m 堆码持续时间：7d Time of stacking:7d
包装件卸到海关库房，然后人工把单个包装件装到运输车辆上 Unload package to warehouse of customs, then load them on transportation cars	水平冲击 Horizontal impact	暖温带 warm temperate zone	水平冲击 Horizontal impact	-	-	-	-
	垂直冲击 Vertical impact		垂直冲击 Vertical impact	-	跌落高度 100mm Drop height::100mm	包装件质量尺寸可装卸性 Package quality dimensions can be loading and unloading	跌落高度 100mm Drop height::100mm

用带篷汽车将包装件经公路运到目的地（距离 50km） Transfer package through road to destination(distance 50km)	振动 vibration	暖温带 warm temperate zone	振动 vibration	-	堆码高度：3.0m Height of stacking:3.0m 振动持续时间：20min Time of vibration :20min	托盘承载单元 Pallet loaded unit	堆码高度：3.0m Height of stacking:3.0m 振动持续时间：20min Time of vibration :20min
	堆码 stacking		堆码 stacking	-	堆码高度：3.0m Height of stacking:3.0m 堆码持续时间：1d Time of stacking:1d		堆码高度：3.0m Height of stacking:3.0m 堆码持续时间：1d Time of stacking:1d
	水平冲击 Horizontal impact		水平冲击 Horizontal impact	-	速度 1.5m/s Speed:1.5m/s		速度 1.5m/s Speed:1.5m/s
终点卸下包装件 Unload package at destination	垂直冲击 Vertical impact	暖温带 warm temperate zone	垂直冲击 Vertical impact	-	跌落高度 100mm Drop height::100mm	包装件质量尺寸可装卸性 Package quality dimensions can be loading and unloading	跌落高度 100mm Drop height::100mm

3、试验顺序和试验强度

按照 GB/T 4857.3 idt ISO 2234：2000 做堆码试验 堆码高度：3.0m、堆码持续时间：7d

According to GB/T 4857.3 idt ISO 2234: stacking experiment is done for 2000, the height of stacking:3.0m, time of stacking:7d

按照 GB/T 4857.5 idt ISO 2248-1985 做跌落试验 跌落高度：300mm 每一包装件试验 2 次

According to GB/T 4857.5 idt ISO 2248-1985 the drop experiment ,drop height :300mm, 2 times per package

按照 GB/T 4857.7 idt ISO 2247:2000 做振动试验 堆码高度：3.0m 振动持续时间：60min

According to GB/T 4857.7 idt ISO 2247: vibration experiment is done for 2000, stacking height:3.0 lasting time:60min

按照 GB/T 4857.11 idt ISO 2244:2000 做水平冲击试验 冲击速度：1.5m/s，第 3 面为置放面，在第 3 和第 6 面上进行冲击. 抽样数 5 个

According to GB/T 4857.11 idt ISO 2244: horizontal experiment is done for 2000, impact speed:1.5m/s, the third side implantation surface, and should impact on the third and sixth side. 5should be sampled.

4、结论 conclusion

试验顺序 sequence of test	试验方法 method of test	试验强度 strength of experiment	结果 result
堆码试验 stacking test	GB/T 4857.3 idt ISO 2234：2000	堆码高度：3m、堆码持续时间：7d Height of stacking:3m lasting time of stacking:7d	符合 fill
跌落试验 Drop test	GB/T 4857.5 idt ISO 2248-1985	跌落高度：300mm 每一包装件试验 2 次 Drop height:300mm 2times per package	符合 fill
振动试验 Vibration test	GB/T 4857.7 idt ISO 2247:2000	堆码高度：3.0m 振动持续时间：60min Height of stacking:3m lasting time of stacking:60min	符合 fill
水平冲击试验 Horizontal impact test	GB/T 4857.11 idt ISO 2244:2000	冲击速度：1.5m/s Impact speed:1.5m/s	符合 fill

attachment number：CE-01-07

attachment number：CE-01-07

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Technical File(技术文档)	**Version(版号): A/**0
	Number(编号): CE-01-07
符合基本要求表 93/42/EEC including 2007/47/EC Annex I Essential Requirements Checklist93/42/EEC 包括 2007/47/EC 附录一	**Chapter(章): 07**
	Pages(页): 1

Product name: 产品名称：	**Heat Pads**		
Type(s)/Model(s): 类型/型号	TYPE Class IIa		
Product group: 产品族	**Heat Pads**		
Issue date of Technical File: 技术文档发布日：	2015-11-25	Revision of Technical File: 技术文档修订版本：	A/0
Legal Manufacturer: 法定生产者	*Name 名字* Henan Hexin Hengda Industrial Co., Ltd. 邮编 464000 *地点* Add: East Lake Hengda Industrial park Shihe District 464000 Xinyang City,Henan China		
Accessories: 附件：			

Date 日期		Name Reviewer 1/审核人 1 的名字		Signature Reviewer 1/审核人 1 签字
Date 日期		Name Reviewer 2/审核人 2 的名字		Signature Reviewer 2/审核人 2 签字

Checklist according to annex I of the Medical Device Directive(MDD)按医疗器械指令（MDD）附录一的基本要求		A/NA 适用/不适用	Standards, other directives and other rules applied by manufacture 生产者引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，条例,文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body)要求满足(由公告机构填写)	Ok / Fail 符合/不符合
I.	General Requirements 总要求					
1.	The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety. 器械的生产和设计必须保证：按照其预定功能和条件使用，器械不会损害医疗环境、患者安全、或操作者或其它人员的安全和健康；假设与器械预定使用功能相关的任何风险，与之带来的益处相比是可接受的，则与健康安全的保护程度相适应。 This shall include: reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and	A	EN ISO 15223-1-2012 EN ISO 14971:2012 Company standards QB/ HENGDA-001-2014	08.2Labeling (标签) 20 Test Reports (testing laboratories, reports)测试报告 10 Risk Management Report (风险分析报告)		

Checklist according to annex I of the Medical Device Directive(MDD)按医疗器械指令（MDD）附录一的基本要求		A/NA 适用/不适用	Standards, other directives and other rules applied by manufacture 生产者引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，条例,文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body)要求满足(由公告机构填写)	Ok / Fail 符合/不符合
	consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users). 应包括： 尽可能地降低由于器械的人体工学特征和器械使用的环境（为患者安全设计的）的错误使用而产生的风险， 和考虑技术知识、经验、教育和培训，预期用户（为非专业人员、专业人员、伤残人员或其它人）的医疗和身体条件。					
2.	The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order: eliminate or reduce risks as far as possible (inherently safe design and construction), where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,	A	EN ISO 14971:2012 EN ISO 15223-1-2012 Company standards QB/ HENGDA-001-2014	08.2Labeling (标签) 20 Test Reports (testing laboratories, reports)测试报告 10 Risk Management Report (风险分析报告)		

Checklist according to annex I of the Medical Device Directive(MDD)按医疗器械指令（MDD）附录一的基本要求		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacture 生产者引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，条例,文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body)要求满足(由公告机构填写)	Ok / Fail 符合/不符合
	Inform users of the residual risks due to any shortcomings of the protection measures adopted. 生产者的设计和制造方案时必须，必须考虑在现有工艺技术条件下遵守安全准则。 在选择最合适方案时，生产者应按照以下顺序遵守准则： 尽可能地降低甚至避免危险 （本质上的安全设计和结构） 对无法避免的危险采取适当的防护措施，包括安装报警装置。 告知用户所提供防护措施的弱点及其可能带来的危险。					
3.	The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer. 器械最后必须取得生产者期望获得的功能。器械设计制造和包装应有利于第1条(2)(a)所规定的一项或多项功能的发挥。	A	EN ISO 13485:2012 Company standards QB/ HENGDA-001-2014	Company Test Report 20 Test Reports (testing laboratories, reports)测试报告		
4.	The characteristics and performances referred to in sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical condition and safety of the patients and, where applicable, of other persons are compromised during the lifetime	A	EN ISO 13485:2012 Company standards QB/ HENGDA-001-2014	Company Test Report 20 Test Reports (testing laboratories,		

Checklist according to annex I of the Medical Device Directive(MDD)按医疗器械指令（MDD）附录一的基本要求		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacture 生产者引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，条例,文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body)要求满足(由公告机构填写)	Ok / Fail 符合/不符合
	of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use. 在生产者确定的器械使用寿命期内，在正常使用可能出现的压力下，第1，2，3款指的各项性能应保持稳定，不能危害医疗环境、危害患者、使用者或其它人员的健康。			reports)测试报告		
5.	The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer. 器械设计、生产和包装应当保证器械的性能在运输和储存过程中只要遵守有关规定不会发生根本逆转。	A	EN ISO 13485:2012 Company standards QB/ HENGDA-001-2014	Company Test Report 20 Test Reports (testing laboratories, reports)测试报告		
6.	Any undesirable side effects must constitute an acceptable risk when weighed against the performances intended. 副作用的大小同器械的使用性能相比可以为人们所接受	A	EN ISO 14971:2012	10 Risk Management Report (风险分析报告)		
6a.	Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X. 证明符合基本要求必须包括按照附录X的临床评估	A	EN ISO 14971:2012	14 Clinical Investigation 临床调查		

Checklist according to annex I of the Medical Device Directive(MDD)按医疗器械指令（MDD）附录一的基本要求		A/NA 适用/不适用	Standards, other directives and other rules applied by manufacture 生产者引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，条例,文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body)要求满足(由公告机构填写)	Ok / Fail 符合/不符合
II.	REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION 设计和结构的要求					
7.	Chemical, physical and biological properties 化学、物理和生物特征					
7.1	The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section 1 on the "General requirements". Particular attention must be paid to: the choice of materials used, particularly as regards toxicity and, where appropriate flammability, the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device. Where appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand. 器械的设计和生产必须保证达到本附录第Ⅰ部分的一般要求，另外应注意： 合理选择原料，特别是易燃物质和有毒物质的选择； 从器械预定功能出发考虑所选材料同人体生物组织、细胞和血液的相容性。	A	EN ISO 14971:2012	19 Product Material Conformity Declaration 产品/材料的符合性证明 10 Risk Management Report（风险分析报告）		

Checklist according to annex I of the Medical Device Directive(MDD)按医疗器械指令（MDD）附录一的基本要求		A/NA 适用/不适用	Standards, other directives and other rules applied by manufacture 生产者引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，条例,文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body)要求满足(由公告机构填写)	Ok / Fail 符合/不符合
	如果适用，事先已确认有效的生物物理学或模型研究的结果					
7.2	The devices must be designed, manufactured and packed in such a way as to minimise the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and the duration and frequency of the exposure. 器械的设计、制造和包装应当保证器械运输、储存和使用过程中的遗留物对人体危害最低，应特别注意观察暴露于器械下的人体组织及其时间和次数。	A	EN ISO 15223-1-2012 EN ISO 14971:2012	19 Product Material Conformity Declaration 产品/材料的符合性证明 10 Risk Management Report（风险分析报告）		
7.3	The devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing those products and that their performance is maintained	NA		不加载某种物质 Does not load a substance		

Checklist according to annex I of the Medical Device Directive(MDD)按医疗器械指令（MDD）附录一的基本要求		A/NA 适用/不适用	Standards, other directives and other rules applied by manufacture 生产者引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，条例,文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body)要求满足(由公告机构填写)	Ok / Fail 符合/不符合
	in accordance with the intended use. 器械设计和生产必须保证在正常使用过程中接触其它材料、物质和气体不会影响其安全使用；如果器械需要加载其它药品，器械的设计和生产必须保证同该药品、器械的设计和生产必须保证同该药品相兼容，必须考虑发法律对该药品的规定和限制，保证器械达到预定功能。					
7.4	Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC. 如果某种器械含有某种物质作为其组成部分，而且该物质单独使用时可被认为是 2001/83EC 第 1 条含义内的药品，并且它能够帮助该器械对人体产生辅助作用，这种物质的安全性、质量和有效性必须通过 2001/83EC 指令附录 I 涉及的适用方法进行类推来确认。 For the substances referred to in the first paragraph, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended	NA		不加载某种物质 Does not load a substance		

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	purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States or the European Medicines Agency (EMEA) acting particularly through its committee in accordance with Regulation (EC) No 726/2004[1] on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing its opinion, the competent authority or the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. 对于第一段提到的物质，在考虑到该器械的预期用途时确认了该物质作为医疗器械一部分的有效性并后，公告机构应按 Regulation (EC) No 726/2004 法规，就该物质的质量和安全性包括该物质与器械整合的临床收益/风险属性，向成员国指定的一个主管当局或欧洲药品评价署（EMEA）特别是其委员会寻求科学意见。当发表其意见时，主管当局或 EMEA 应考虑公告机构认定的生产过					

[1] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1). Regulation as last amended by Regulation (EC) No 1901/2006.

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	程和关于该物质与器械整合的有效性。 Where a device incorporates, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking into account the intended purpose of the device, seek a scientific opinion from the EMEA, acting particularly through its committee, on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing this opinion, the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. 如果某种器械含有人血制品作为其组成部分，在确认了该制品作为医疗器械一部分的有效性，并考虑到该器械的预期用途的基础上，公告机构应就该制品的质量和安全性包括该制品与器械整合的临床收益/风险属性，向欧洲药品评价署（EMEA）特别是其委员会寻求科学意见。当发表其意见时，主管当局或 EMEA 应考虑公告机构认定的生产过程和关于该物质与器械整合的有效性。	NA		不含人血制品 Without human blood products		

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	Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained. The competent authority shall take into account the data related to the usefulness of incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the medical device. 如果器械整合的辅助物质发生了变更，特别是关系到其生产过程，公告机构应被通知并向相关的药品主管当局（也就是最初的咨询机构）咨询，以确认辅助物质的质量和安全性得以维持。主管当局应考虑公告机构认定的关于该物质与器械整合的有效性，以确保这种变更对已经建立的医疗器械中的增加物质的临床收益/风险属性没有负面影响。 When the relevant medicines competent authority (i.e. the one involved in the initial consultation) has obtained information on the ancillary					

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	substance, which could have an impact on the established benefit/risk profile of the addition of the substance in the medical device, it shall provide the notified body with advice, whether this information has an impact on the established benefit/risk profile of the addition of the substance in the medical device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure. 当相关的药品主管当局（也就是最初的咨询机构）得到关于辅助物质对已经建立的医疗器械中的增加物质的临床收益/风险属性有影响的信息后，应向公告机构提出忠告，该信息是否影响已经建立的医疗器械中增加物质的临床收益/风险属性。公告机构应考虑到更新的科学意见，以重新考虑对符合性评价程序的评价。					
7.5	The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex I to Council Directive	A	EN ISO 15223-1-2012 EN ISO 14971:2012	19 Product Material Conformity Declaration 产品/材料的符合性证明 10 Risk Management Report（风险分析报告）		

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	67/548/EEC[2] of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances[3]. 器械必须设计和制造得将源自器械的物质泄漏的风险降至最低。应当特别注意按 1967 年 6 月 27 日成员国法律中 67/548/EEC 委员会指令附录 I 界定的致癌物、诱基因突变物和繁殖毒性物质。 If parts of a device (or a device itself) intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC[2], these devices must be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates. 如果器械的一部分（或器械本身）预期用于对身体给药	A	EN ISO 15223-1-2012 EN ISO 14971:2012	19 Product Material Conformity Declaration 产品/材料的符合性证明 10 Risk Management Report（风险分析报告）		

[2] Internal note: replaced by (EC) 1272/2008

[3] OJ 196, 16.8.1967, p. 1. Directive as last amended by Directive 2006/121/EC of the European Parliament and of the Council (OJ L 396, 30.12.2006, p. 850).

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	或除药、体液或其它物质，或预期用于运输或存储这些体液或物质，包含有按67/548/EEC指令附录I界定的1类或2类致癌物、诱基因突变物或繁殖毒性物质的邻苯二甲酸酯，该器械必须在自身和/或每台的包装上作出标识，及适当时在器械的销售包装上作出含有邻苯二甲酸酯的标识。 If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide a specific justification for the use of these substances with regard to compliance with the essential requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures. 如果器械的预期用途包括对儿童、孕妇或哺乳期妇女的治疗，制造商必须在技术文档和使用说明书中提供具体的使用这些物质并符合基本要求、特别是本条的理由，和对这些病患人群的残余风险及适当时预警措施的信息。					
7.6	The devices must be designed and manufactured in such a way as to reduce as much as possible, risks posed by the unintentional ingress of substances	A	EN ISO 15223-1-2012 EN ISO 14971:2012	19 Product Material Conformity Declaration 产品/材		

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	into the device taking into account the device and the nature of the environment in which it is intended to be used. 考虑器械使用的环境和其它配套器械，器械的设计和生产必须保证，最大限度地降低由于异物进入而造成危害的可能性。			料的符合性证明 10 Risk Management Report（风险分析报告）		
8.	Infection and microbial contamination 感染和微生物污染					
8.1	The devices and their manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimise contamination of the device by the patient or vice versa during use. 器械设计和制造工艺应当保证最大限度地降低甚至避免患者、使用者和其它人员之间交叉感染的可能性；器械应当操作简单，减少患者对器械、器械对患者的接触污染。	A	EN ISO 15223-1-2012 EN ISO 14971:2012	19 Product Material Conformity Declaration 产品/材料的符合性证明 10 Risk Management Report（风险分析报告）		
8.2	Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues.	NA		No animal organs（无动物器官）		

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	动物器官必须根据使用目的接受检疫管理和监督。 Notified Bodies shall retain information on the geographical origin of the animals. 指定认证结构应了解动物的原生地。 Processing, preservation, testing and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal security. In particular safety with regard to viruses and other transmissible agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process. 动物组织、细胞和其它组织成份必须进行加工、贮存、检验和控制，提供最可靠的安全保障。特别是病毒和其它传染物质。在生产过程中有采取有效措施进行消毒灭菌。					
8.3	Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened. 无菌器械的设计、生产和包装应采用一次性使用包装方	NA		Does not belong to the sterile equipment 不属于无菌设备		

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	式，并且在一定工作程序下保证器械上市时处于无菌状态，在贮藏、运输条件下只要包装不破损或开封，能够保持无菌状态。					
8.4	Devices delivered in a sterile state must have been manufactured and sterilised by an appropriate, validated method. 无菌器械必须通过专门、有效的方法进行生产和灭菌。	NA		Does not belong to the sterile equipment 不属于无菌设备		
8.5	Devices intended to be sterilised must be manufactured in appropriately controlled (e.g. environmental) conditions. 需要灭菌的器械在专门控制的环境下生产。	NA		Does not belong to the sterile equipment 不属于无菌设备		
8.6	Packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilised prior to use, minimise the risk of microbial contamination. The packaging system must be suitable taking account of the method of sterilisation indicated by the manufacturer. 非灭菌器械的包装设备，应当保证产品达到规定的清洁度，减少器械灭菌前微生物污染的可能性。包装设备必须适合于生产者所指定的灭菌方式。	NA		Does not belong to the sterile equipment 不属于无菌设备		
8.7	The packaging and/or label of the device must distinguish between identical or similar products	NA		Does not belong to the sterile		

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	sold in both sterile and non-sterile condition. 相同或相似的产品销售时处于无菌状态还是非无菌状态，必须具有不同的包装或标签。			equipment 不属于无菌设备		
9.	Construction and environmental properties 结构和环境特征					
9.1	If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performance of the devices. Any restrictions on use must be indicated on the label or in the instruction for use. 器械如果需要同其它器械或设备配合在一起使用，应保证安全，包括联接件必须安全，不得改变器械的预定功能。必须在使用说明或标签上注明使用限制。	NA		Do not need to cooperate with other equipment 不需要配合其它设备使用		
9.2	Devices must be designed and manufactured in such a way as to remove or minimise as far as possible: 器械的设计和生产必须保证降低或避免： the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional, and where appropriate the ergonomic features, 由于器械物理性能特性，如体积压力比、外观尺寸、人机工程等特性，对人体造成伤害的可能性。	A	EN ISO 15223-1-2012 EN ISO 14971:2012	10 Risk Management Report（风险分析报告）		

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	risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure, and acceleration, 在合理的环境条件下，如电磁场、电子干扰，静电放射、大气压、气温以及压力变化和加速度等条件下，对人体造成伤害的可能性。 the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given, 在使用或试用时，同其它器械相互干扰对人体造成伤害的可能性。 risks arising where maintenance or calibration are not possible (as with implants) from ageing of the materials used or loss of accuracy of any measuring or control mechanism. 如果无法维修或矫正(如植入人体后),由于材料老化、测试或控制机能精度不够，对人体造成伤害的可能性。					

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9.3	Devices must be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention must be paid to devices whose intended use includes exposure to flammable substances which could cause combustion. 器械的设计和生产必须保证，在正常使用情况下或单项操作出现错误的情况下，器械不至于起火或爆炸。对在暴露于易燃物质或起火物质环境下使用的器械必须给予特别注意。	NA		The equipment will not fire or explosion 设备不会起火或爆炸		
10.	Devices with a measuring function 具有测量功能的器械					
10.1	Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer. 检测器械的设计和生产必须保证足够的精度和稳定性、符合器械预定功能的要求。生产者必须注明其精度范围。	NA		Does not belong to the measuring equipment 不属于测量设备		
10.2	The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the	NA				

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	device. 必须根据器械的预定功能，按照人机过程的原理设计器械的度量、监控和显示方式。					
10.3	The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC[4]. 测量器械必须使用法定度量单位，符合理事会法令80/181/EEC的规定。	NA		Does not belong to the measuring equipment 不属于测量设备		
11.	Protection against radiation 辐射保护					
11.1 11.1.1	*General* *原则* Devices shall be designed and manufactured such that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes. 器械的设计和生产必须保证在达到预定功能的情况下，尽量减少对患者、使用者和其它人员的辐射，但不限制为治疗和诊断疾病使用规定合理的剂量。	NA		No radiation 无辐射		

[4] OJ No L 39, 15. 2. 1980, p. 40. Directive as last amended by Directive 89/617/EEC (OJ No L 357, 7. 12. 1989, p. 28).

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11.2 11.2.1	*Intended radiation* *设计辐射* Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters. 用于特定医疗目的，有的器械辐射危害人体健康的射线，这种器械对患者的治疗作用同射线相比可以为人们所接受。器械辐射剂量必须能够控制，(设计和生产时)必须考虑其可变参数的可重复性和容差。	NA		No radiation 无辐射		
11.2.2	Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be fitted, where practicable, with visual displays and/or audible warnings of such emissions. 设计器械发射危害性射线，不论射线是否可见，都应根据实际需要安装可见的显示装置和发声的报警装置，指示射线的发射状态。	NA		No radiation 无辐射		
11.3	*Unintended radiation* *非设计辐射*	NA		No radiation 无辐射		

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11.3.1	Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is be reduced as far as possible. 器械的设计和制造应当保证，尽量减少对患者，使用者以及其它人员产生非设计的意外辐射。					
11.4 11.4.1	*Instructions* *使用说明* The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation. 放射性医疗器械应详细说明辐射特性、对患者和操作者的保护措施、任何防止操作错误以及消除由于安装器械带来的潜在危险。	NA		No radiation 无辐射		
11.5 11.5.1	*Ionising radiation* *电离辐射* Devices intended to emit ionising radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and	NA		No radiation 无辐射		

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	quality of radiation emitted can be varied and controlled taking into account the intended uses. 电离辐射器械的设计和生产必须保证，可以改变和控制电离辐射的数量，形状和质量，满足预定使用功能的实际需要。					
11.5.2	Devices emitting ionising radiation intended for diagnostic radiology shall be designed and manufactured in such a way, as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimising radiation exposure of the patient and user. 诊断用电离辐射器械的设计和生产必须保证，在获得清晰图象、提高输出质量、达到预定医疗目的的情况下，尽量减少对患者和使用者的照射。	NA		No radiation 无辐射		
11.5.3	Devices emitting ionising radiation intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the quality of the radiation. 治疗用电离辐射器械的设计和生产必须保证，能够有效地监控照射剂量、离子束类型、能量大小以及离子束的质量。	NA		No radiation 无辐射		

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12.	Requirements for medical devices connected to or equipped with an energy source 连接或装备能源的医疗器械的要求					
12.1	Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to their intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks 带有可编程系统的器械设计应保证其可重复性、可靠性、满足预定功能的需要。应当采取必要措施、减少因出现个别错误造成危害的可能性。	NA		No programming system 无可编程系统		
12.1a	For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification. 对于合并软件使用的或本身是医疗软件的器械，软件必须考虑研发生命周期、风险管理、确认和验证的原则，按照当今的先进水平进行确认。	NA		Non software medical devices 非软件医疗器械		
12.	Devices where the safety of the patients depends on	NA		Non electrical		

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2	an internal power supply must be equipped with a means of determining the state of the power supply. 对维系患者安全的器械，内部供电时，应配有电源指示装置，表明电源的供电状况。			equipment 非带电医疗器械		
12.3	Devices where the safety of the patient depends on an external power supply must include an alarm system to signal any power failure. 对维系患者安全的器械，外部供电时，应增加报警装置，报告电源中断。	NA		Non electrical equipment 非带电医疗器械		
12.4	Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health. 监测患者临床数据的器械，必须配置相应的报警系统，提醒操作者可能导致患者死亡或病情严重恶化的情况。	NA		Non monitoring medical devices 非监视医疗器械		
12.5	Devices must be designed and manufactured in such a way as to minimise the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment. 器械的设计和生产必须保证，尽量减少由于产生电磁场，影响其它器械或设备的操作使用造成的危害。	NA		Non electrical equipment 非带电医疗器械		

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12.6	*Protection against electrical risks* *防止触电危险.* Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided that the devices are installed correctly. 假定器械安装正确，器械的设计和生产必须尽量减少在正常使用和出现个别错误时，意外电击的危险	NA		Non active medical device 非有源医疗器械		
12.7 12.7.1	*Protection against mechanical and thermal risks* *高温和机械防护* Devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance, stability and moving parts. 器械的设计和生产必须保证患者、使用者不受机械部件造成的损伤，如阻力部件、稳定性部件和移动性部件造成的损伤。	NA		Not resistance, stability and mobility parts		
12.7.2	Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations,	NA		No vibration		

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	particularly at source, unless the vibrations are part of the specified performance. 器械的设计和生产必须保证，根据技术发展水平，采取控制振动(特别是振动源)的措施，最大限度地降低器械振动造成的危害，除非所发出的振动是特定功能的需要。					
12.7.3	Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance. 器械的设计和生产必须保证，根据技术发展水平，采取控制噪音(特别是噪音源)的措施，最大限度地降低器械噪音造成的危害，除非所发出的声音是特定功能的需要。	NA		No noise 无噪音		
12.7.4	The terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and constructed in such a way as to minimise all possible risks. 操作者接触的电源、气动、气压端口和连接件，设计和生产必须考虑减少各种危险的可能性。	NA		No power, pneumatic, pneumatic ports and connectors 没有电源、气动、气压端口和连接件		
12.7.5	Accessible parts of devices (excluding any parts or areas intended to supply heat or reach given temperatures) and their surroundings must not	NA		Is specialized in supplying heat equipment 是专门提		

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	attain potentially dangerous temperatures under normal use. 在正常使用的情况下，人体可接触到的器械部件及其周围，温度不得过高，以免造成危险；但不包括专门用于提供热量或必须达到一定温度的部件和区域。			供热量的设备		
12.8 12.8.1	Protection against the risks posed to the patient by energy supplies or substances 防止能源和营养供应造成的危险 Devices for supplying the patient with energy or substances must be designed and constructed in such a way that the flow rate can be set and maintained accurately enough to guarantee the safety of the patient and of the user. 为患者提供能源和营养的器械设计和生产必须保证，器械可以控制流量，保证足够的精度，保证患者和使用者的安全。	NA		Didn't need to control flow 不需要控制流量		
12.8.2	Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate which could pose a danger. 器械必须配有专门装置，防止出现流量波动给患者带来危险，或出现问题时报警。 Devices must incorporate suitable means to prevent, as far as possible, the accidental release of	NA		Didn't need to control flow 不需要控制流量		

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	dangerous levels of energy from an energy and/or substance source. 器械必须配备适当的装置尽量避免能量或营养流量意外增加到危险的程度。					
12.9	The function of the controls and indicators must be clearly specified on the devices. 指示器和控制按钮、手柄等必须在器械上予以注明。 Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient. 如果器械通过可视系统提供操作说明，通过可视系统显示和修改各种参数，可视系统显示的信息必须能为操作者所理解，必要时患者也应看得懂。	NA		Non active medical device，Not indicators and control buttons, handle 非有源医疗器械,没有指示器和控制按钮、手柄		
13.	Information supplied by the manufacturer 生产者提供的信息					
13.1	Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer. 考虑到对于潜在使用者的培训和认知，以及识别生产者，每个器械必须附带所需信息，以安全正确使用。	A	EN 1041:2008 EN ISO 15223-1-2012	08.2Labeling (标签) 08.3 Users manual, instruction for Use 产品说明书		

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	This information comprises the details on the label and the data in the instructions for use. 这些信息器械应在标签或使用说明书具体说明。 As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices. 根据实际需要，在器械上、在每个器械的包装上或在销售包装上都应注明安全使用所需要的操作信息。如果不可能对每个器械单独包装，则应随每一个器械或一定数量的器械提供活页说明。 Instructions for use must be included in the packaging for every device. By way of exception, no such instruction leaflet is needed for devices in Class I or Class IIa if they can be used completely safely without any such instructions. 每个器械的包装中应附带使用说明，但 I 类或 IIa 类器械，如果不需要使用说明书也可以安全使用，可以除外。					
13.2	Where appropriate, this information should take the form of symbols. Any symbol or identification colour	A	EN 1041:2008 EN ISO 15223-1-2012	08.2Labeling (标签) 08.3 Users manual,		

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	used must conform to the harmonised standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device. 根据需要应通过使用标志说明操作信息。器械使用的标志或识别颜色应符合欧洲共同体协调标准。如果没有统一标准，标志和识别颜色的含义必须在器械附带的资料中说明。			instruction for Use 产品说明书		
13.3	The label must bear the following particulars: 器械标签必须具有下列内容： a) the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of the authorised representative where the manufacturer does not have a registered place of business in the Community; (a)生产者的名称或商品名以及地址。为了在欧洲共同体内发行，如果生产者在欧共体内没有注册场地，则进口的器械标签、外包装和使用说明应另外注明授权代表的名称和地址。 b) the details strictly necessary to identify the device and the contents of the packaging especially	A	EN 1041:2008 EN ISO 15223-1-2012	08.2Labeling (标签) 08.3 Users manual, instruction for Use 产品说明书		

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	for the users; (b) 使用者识别器械和了解包装内容必需的信息； c) where appropriate, the word "STERILE"; (c)必要时，注明“已灭菌”字样； d) where appropriate, the batch code, preceded by the word "LOT", or the serial number; (d)必要时，注明批号或系列号，批号以“LOT”打头； e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month; e) 必要时，注明器械安全使用的期限，以年和月表示。 f) where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the Community; f) 必要时，注明器械属于一次性使用。生产者的一次性使用注解必须在欧共体内统一。 g) if the device is custom made, the words "custom made device"; g) 如果属于定作器械，注明“定作器械”字样。 h) if the device is intended for clinical investigations, the words "exclusively for clinical investigations"; h) 如果属于临床试用的器械，注明“专门用于临床试用”字样					

Checklist according to annex I of the Medical Device Directive(MDD)按医疗器械指令（MDD）附录一的基本要求		A/NA 适用/不适用	Standards, other directives and other rules applied by manufacture 生产者引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，条例,文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body)要求满足(由公告机构填写)	Ok / Fail 符合/不符合
	i) any special storage and/or handling conditions; i) 特殊储存和管理要求; j) any special operating instructions; j) 特殊操作说明; k) any warnings and/or precautions to take; k) 注意事项 l) year of manufacture of active devices other than those covered by e). This indication may be included in the batch or serial number; l) 器械的生产日期，不为(e)项所含，但可以包含在批号或系列号内。 m) where applicable, method of sterilisation. m)必要时，注明灭菌方法。 n) in the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative.″ n) 若器械涉及第一章1(4a)条款，注明器械含有人血制品					
13.4	If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use. 如果操作者对器械的预定功能不了解，生产者在标签和操作说明上应当加以注明。	A	EN 1041:2008 EN ISO 15223-1-2012	08.2Labeling (标签) 08.3 Users manual, instruction for Use 产品说明书		

Checklist according to annex I of the Medical Device Directive(MDD)按医疗器械指令（MDD）附录一的基本要求		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacture 生产者引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，条例,文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body)要求满足(由公告机构填写)	Ok / Fail 符合/不符合
13.5	Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components. 器械和可拆卸部件必须加以识别，如果需要，可以采取各种有效方法对频批量器械和拆卸部件加以测试，排除隐患。	NA		No detachable parts		
13.6	Where appropriate, the instructions for use must contain the following particulars: 若适用，使用说明书必须包含以下说明： a) the details referred to in 13.3, with the exception of d) and e) a) 本附录第13.3款所指除(d)和(e)项以外的各项内容； b) the performances referred to in section 3 and any undesirable side effects; b) 本附录第3款所指使用性能及其可能带来的副作用。 c) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination; c) 如果必须同其它器械或设备一同安装或连接使用，	A	EN 1041:2008 EN ISO 15223-1-2012	08.2Labeling (标签) 08.3 Users manual, instruction for Use 产品说明书		

Checklist according to annex I of the Medical Device Directive(MDD)按医疗器械指令（MDD）附录一的基本要求	A/NA 适用/不适用	Standards, other directives and other rules applied by manufacture 生产者引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，条例,文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body)要求满足(由公告机构填写)	Ok / Fail 符合/不符合
应当说明配合使用的器械或设备的特性，以便取得预期的功能。 d) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times; d) 鉴别器械是否正确安装所必要的技术信息，保证准确、安全使用；以及维护和校准器械所必须的技术指标或频率，保证器械长期准确、安全使用。 e) where appropriate, information to avoid certain risks in connection with implantation of the device; e) 对植入人体的器械，如果需要，应加以特别说明，避免出现植入人体器械特有的危险。 f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment; f) 在进行特殊检查和治疗的过程中，器械产生相互干扰的危险性说明。 g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of re-sterilisation g) 说明灭菌包装损坏后，器械如何进行处理；如果可					

Checklist according to annex I of the Medical Device Directive(MDD)按医疗器械指令（MDD）附录一的基本要求	A/NA 适用/不适用	Standards, other directives and other rules applied by manufacture 生产者引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，条例,文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body)要求满足(由公告机构填写)	Ok / Fail 符合/不符合
能，说明重新灭菌的有效方法。 h) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of he device to be resterilized, and any restriction on the number if reuses. Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section I). If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. If in accordance with Section 13.1 no instructions for use are needed, the information must be made available to the user upon request; h) 可重复使用的器械，应说明准确使用的方法，包括清扫、防止传染、包装以及对需要消毒的器械进行灭菌的方法，重复使用的次数限制。 如果器械预期要在使用前灭菌，清洁和灭菌的使用说明					

Checklist according to annex I of the Medical Device Directive(MDD)按医疗器械指令（MDD）附录一的基本要求	A/NA 适用/不适用	Standards, other directives and other rules applied by manufacture 生产者引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，条例,文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body)要求满足(由公告机构填写)	Ok / Fail 符合/不符合
要做到如果正确遵守，器械仍符合第 1 部分的要求。 如果器械附带了一次性使用的标识，生产者已知的由于已知特性以及技术因素使器械重复使用带来风险的信息。如果按 13.1 部分的规定不需要使用说明书，则信息必须应使用者要求而提供。					
i) details of any further treatment or handling needed before the device can be used (for example, sterilisation, final assembly, etc.) i) 器械使用前如何进行处理，如灭菌、最后组装等；	NA				
j) in the case of devices emitting radiation for medical purpose, details of the nature, type intensity and distribution of this radiation j) 利用放射线治疗的器械，必须说明放射线的特性、类型、密度和分布	NA				
The instruction for use must also include details, allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular: 使用说明书必须另外说明，当器械出现意外，医护人员如何打消患者顾虑以及注意事项，具体包括：	A	EN ISO 15223-1-2012 EN 1041:2008	08.2Labeling (标签) 08.3 Users manual, instruction for Use 产品说明书		
k) precautions to be taken in the event of changes in the performance of the device; k)器械性能发生变化时的注意事项；	NA				
l) precautions to be taken as regards exposure, in					

Checklist according to annex I of the Medical Device Directive(MDD)按医疗器械指令（MDD）附录一的基本要求		A/NA 适用/不适用	Standards, other directives and other rules applied by manufacture 生产者引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，条例,文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body)要求满足(由公告机构填写)	Ok / Fail 符合/不符合
	reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources etc.; l) 在可预见的使用环境下，在电磁场、外界电流、静电放射、大气压以及大气压发生变化、加速度、热力源等作用下，应当采取的注意事项 m) adequate information regarding the medicinal product or products which the device in question is designed to administer, including any limitations in the choice of substances to be delivered; m) 应当详细说明器械加载的药品或其它物质的性能，包括其选择范围； n) precautions to be taken against any special, unusual risks related to the disposal of the device; n)处置器械时防止出现特别、意外风险的注意事项。 o) medicinal substances, or human blood derivatives incorporated into the device as an integral part in accordance with Section 7.4; o)说明第 7.4 款所指同器械结合一体使用的医药物质或人血制品； p) degree of accuracy claimed for devices with a measuring function.	NA NA NA NA A	EN ISO 15223-1-2012 EN 1041:2008	08.2Labeling (标签) 08.3 Users manual, instruction for Use 产品说明书		

Checklist according to annex I of the Medical Device Directive(MDD)按医疗器械指令（MDD）附录一的基本要求		A/ NA 适用/ 不适用	Standards, other directives and other rules applied by manufacture 生产者引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，条例,文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body)要求满足(由公告机构填写)	Ok / Fail 符合/不符合
	p)具有测试功能的器械应说明期望精度。 q) date of issue or the latest revision of the instructions for use. q) 使用说明书最新版本的修订日期					

See attachment No.: CE-01-8.1

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8.1 目的 Purpose

根据 MDD93/42/EEC 和 EN ISO 14971:2012 的要求分析产品暖贴可能存在的危害和风险，并针对各项风险采取降低措施并经评估后形成报告，从而保证产品存在的危害和风险降低到可以接受的范围，并安全、有效的投放市场。

According to the directive MDD93/42/EEC and EN ISO14971:2012, analysis the heat pads possibility hazards and risk, meanwhile take measures to low the the risks and make assessment report, which ensure the hazards and risks be controlled and acceptable to launch into the market.

8.2 适用标准及文件 Applicable standards and documents

a) ISO14971:2012《医疗器械风险管理—第一部分：风险分析的应用》
ISO14971:2012《Medical Device Risks Management-Part 1:Risk analysis application》

b) KANGDI/QP-9.0-01《风险管理程序》
KANGDI/QP-9.0-01《Risks Management Procedure》

8.3 参与人员 Relevant People

生产部、技质部及供销部各部门负责人。

8.4 产品简介 Product Instruction

Heat Pads are designed to provide immediate heat to help promote therapeutic healing. These portable Heat Pads can be used anytime, anywhere and eliminate the need for electrical heating products.

Heat Pads is the easiest activating Hot Packs available in the market.

8.5 使用方法 Use Instruction

拆开包装袋即激活产品然后贴于内衣上便可使用，有些暖贴可直接贴于皮肤上。

Tear the bags and the heat pads heating air-activated, adhesive the heat pads in the underwear, the panaheat pad can be directly adhesive on the skin.

8.6 产品的预期用途 Product Usage

适用于热的治疗，取暖等.

For heating pain therapy, body warmer etc.

8.7 储存 Storage

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Store at room temperature. Keep away from open flame and extreme temperature conditions. Protect from freezing.

8.8 The scope of risk management

8.8.1 Scope of coverage of devices and accessories:

The plan applies to the entire life cycle of the Hot Packs,Taking risk analysis, risk evaluation, risk control and gather the information in risk management.

8.8.2 Scope of risk management of medical equipment life cycle stages:

(1)、The implementation of the product

(2)、The delivery of products

(3)、Disposal after the delivery of the products

(4)、Disposal of The product scrap (the failure)

8.8.3 **Arrangement for risk management activity**

Phase	Main job description	Responsibilities and Authorities	Requirements on Risk Management Activity Review	Output document
Initial development	1. Identify characteristics related to safety; 2. Identify hazards; 3. Estimate the risk(s) of each hazardous situation; 4. Risk evaluation. 5. Draft the risk control measures plan.	1. Project manager shall organize the implement of activities in this phase; 2. Members of risk management shall be in charge of the job content review.	Project manager shall daft the “risk assessment report ” and organize the review of “risk assessment report”.	1. Risk assessment report.
Prototype phase	1. Verify the implement of risk control measures plan; 2. Assess the residual risk.	1. Project manager shall organize the implement of activities in this phase; 2. Members of risk management shall be in charge of job content review.	Project manager shall draft “report of risk control measures verification and residual risk assessment”, and organize review of the report; Members of risk management shall review the risk management activities in the former phase.	1. Report of risk control measures verification and residual risk assessment report
Design verification and validation	1. Form the risk management report.	1. Project manager shall organize the implement of activities in this phase; 2. Members of risk management shall be in charge of job content review	Members of risk management shall review the risk management activities in former phase.	1. Risk management report
Design change	1. Identify hazards related to design change. 2. Evaluate risk(s) in hazardous	1. Project manager shall organize the implement of activities in this phase.	Project manager shall draft “report of risk management in design change”, and organize the review of	1. Report of risk management in design change;

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	situation which result from design change. 3. Assess risk(s) in design change. 4. Draft the plan of risk control measures for design change. 5.	2. Members of risk management shall be in charge of job content review	this report.	2. Report of risk control measures verification and residual risk assessment in design change.
In and after manufacturing	1. Focus on whether accord with the requirement of regulations and standards, and related production meets the requirements	1. Technology&quality Dept. and Resource development Dept shall collect information about change in regulation; 2. Manufacture Dept. and Technology&quality Dept. shall collect abnormal information in manufacturing and identify and control the hazard.	1. Pay attention to the effectiveness of risk control measures	1. report of risk assessment in and after manufacturing. report of risk control measures verification and residual risk assessment in and after manufacturing.

8.8.4 Team Members and their responsibilities

Name	Department or Position	Duties and responsibilities	Risk position
Wang Zhili	President	Responsible for risk management organization, coordination and audit risk management file	Team leader
Li Ming	Technology&quality Dept. Manager	Responsible for risk analysis, formulation and implementation of risk control measures.	Team members
Zhang Jun	Production department Manager	Be responsible for the implementation of risk control measures and information collection in production.	Team members
Xie Lu	Purchasing&Sales department Manager	Responsible for risk before production and after production products market information collection.	Team members

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8.9 风险的评估标准 Risk Assessment Standard

发生几率 occurrence Probability	严重程度 Severity Grades			
	1）可忽略 disregard	2）一般 general	3）严重 severe	4）灾难 disaster
6）频繁 often	*	N/ACC	N/ACC	N/ACC
5）很可能 possible	*	*	N/ACC	N/ACC
4）偶然 occasional	*	*	*	N/ACC
3）很少 seldom	ACC	ACC	*	*
2）未必可能 unlikelihood	ACC	ACC	*	*
1）难以置信 unbelievable	ACC	ACC	ACC	ACC

8.10 风险等级说明 Risk Grades Instruction

风险等级 Risk Grades	说 明 Instruction
N/ACC	不可接受的风险 Unacceptable risks
*	实现尽可能低的合理水平 achieve a reasonable lowest level
ACC	尽可能接受的风险 acceptable risks

8.11 风险分析模式见“风险管理程序”附件 1。Risk Analysis type please find attachment 1 of “Risk Management Procedure”

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风 险 分 析 报 告

Risk Analysis Report

公司名称： **COMPANY NAME:**	河南核信恒达实业有限公司 HENAN HEXIN HENGDA INDUSTRIAL. CO., LTD.
公司地址： **Company Address:**	Add:East Lake Hengda Industrial park Shihe District 464000 Xinyang City,Henan China
产 品： **PRODUCT:**	暖贴 Heat Pads
型 号： **MODEL:**	10cm x 20cm、10cm x 13cm、9.5cmx13cm、10cm x 8cm、10cm x 7cm、7cm x 9cm, 9.2cmx5.5cm
附 件: **Accessories:**	无
标 准： **PROCEDURE:**	EN ISO 14971:2012
结 论： **RESULT:**	所有可识别的风险都已经被评估。在采取适当的措施以降低这些风险之后，关于产品预期的应用和用途上，各种等级的风险是可以接受的。 All risks associated with the identified hazards have been evaluated. After appropriate measures to reduce these risks have been taken, the overall level of risk of the product is acceptable with regard to the intended application and use of the application.

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Compiled by: (Name/Title/Dept.)	Li Ming Quality Assurance	日期 Date:	2015.11.25
Reviewed by (Name/Title/Dept.)	Zhang Jun Quality Manager	日期 Date:	2015.11.25
Approved by: (Name/Title/Dept.)	Wang Zhili GM	日期 Date:	2015.11.25

特征的定性定量分析： (acc. to EN ISO 14971:2012)
Identification of qualitative and quantitative characteristics (acc. to EN ISO 14971:2012)

序号 Item	影响安全性的特征清单 Lists to identify medical device characteristics that could inpact on safety	特征判定 Characteristics judgment	
1	什么是预期用途/预期目的和怎样使用医疗器械？What is the intend use and how is the medical device to be used?	是 yes	给患者提供热量及热疗效果 Supply patient body warmer and thermal therapy
2	医疗器械是否预期用于植入？ Is the medical device intended to be implanted?	否 no	
3	医疗器械是否预期和患者或其他人员接触？Is the medical device intended to be in contact with the patient or other persons?	否 no	
4	在医疗器械中包含有何种材料和/或成分或与其共同使用、或与医疗器械接触？ What materials or components are utilized in the medical device or are used with , or are in contact with, the medical device?	是 yes	铁粉、蛭石粉、活性炭、盐 Iron powder, vermiculite, activated carbon, salt

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序号 Item	影响安全性的特征清单 Lists to identify medical device characteristics that could inpact on safety	特征判定 Characteristics judgment	
5	是否有能量给予患者或从患者身上吸取? Is energy delivered to or extracted from the patient?	是 yes	提供热量 Supply heating
6	是否有物质提供给患者或从患者身上提取？ Are substances delivered to or extracted from the patient?	否 no	
7	是否由医疗器械处理生物材料然后再次使用? Are biological materials processed by medical device for subsequent reuse, transfusion or transplantation?	否 no	
8	医疗器械是否以无菌形式提供或准备由用户灭菌，或用其他微生物控制方法灭菌? Is the medical devices supplied sterile or intended to be sterilized by the user,or are other microbiological controls applicable?	否 no	
9	医疗器械是否预期由用户进行常规清洁和消毒? Is the medical device intended to be routinely cleaned and disinfected by the user?	否 no	
10	医疗器械是否预期改善患者的环境? Is the medical device intended to modify the patient environment?	否 no	
11	是否进行测量? Are measurements taken?	否 no	

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序号 Item	影响安全性的特征清单 Lists to identify medical device characteristics that could inpact on safety	特征判定 Characteristics judgment	
12	医疗器械是否进行分析处理？Is the medical device interpretative?	否 no	
13	医疗器械是否预期和医药或其他医疗技术联合使用？It the medical device intended for use in conjunction with other medical devices,medicines or other medical technologies?	否 no	
14	是否有不希望的能量或物质输出？ Are there unwanted outputs of energy or substances?	否 no	
15	医疗器械是否的对环境影响敏感？ Is the medical device susceptible to environmental influences?	否 no	
16	医疗器械是否影响环境？ Does the medical device influence the environment?	否 no	
17	医疗器械是否有基本消耗品和附件？ Are there essential consumables or accessories associated with the medical device?	否 no	
18	是否需要维护和校准？ Is maintenance or calibration necessary?	否 no	
19	医疗器械是否有软件？ Does the medical device contain software?	否 no	

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序号 Item	影响安全性的特征清单 Lists to identify medical device characteristics that could inpact on safety	特征判定 Characteristics judgment	
20	医疗器械是否有储存寿命限制？ Does the medical device have a restricted shelf-life?	是 yes	看使用说明书 See user manual
21	是否有延迟和/或长期使用效应？应考虑的因素包括人机工程学和累积的效应。 Are there any delayed or long-term use effects?	否 no	
22	医疗器械承受何种机械力？ To what mechanical forces will the medical device be subjected?	否 no	
23	是什么决定医疗器械的寿命？ What determines the lifetime of the medical device?	是 yes	包装袋的寿命 The lifetime of the packing bag
24	医疗器械是否预期一次性使用？ Is the medical device intended for single use?	是 yes	看使用说明书 See user manual
25	医疗器械是否需要安全的退出运行或处置？ Is sate decommissioning or disposable of the medical device necessary?	否 no	
26	医疗器械的安装或使用是否要求专门的培训？ Does installation or use of the medical device require special training or special skills?	否 no	
27	是否需要建立或引入新的生产过程？ Will new manufacturing processes need	否 no	

Technical File(技术文档)	**Version(版号): A/0**
	Number(编号): CE-01-08
风险分析报告 Risk Analysis Report	**Chapter(章): 08**
	Pages(页): 10

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序号 Item	影响安全性的特征清单 Lists to identify medical device characteristics that could inpact on safety	特征判定 Characteristics judgment	
	to be established or introduced?		
28	安全使用信息是如何提供的? How will information for safe use be provided?	是 yes	在产品说明书中提供安全使用信息。 Please see product directions and cautions
29	医疗器械的成功使用,是否决定性的取决于人为因素,例如使用者接口? Is successful application of the medical device critically dependent on human factors such as the user interface?	否 no	
29.1	用户接口的设计特征是否可能导致使用错误 ?Can the user interface design features contribute to use error?	否 no	
29.2	在器械的使用环境中, 是否会因分心而导致使用错误? Is the medical device used in an environment where distractions can cause use error?	否 no	
29.3	医疗器械是否有连接部件或附件? Does the medical device have connecting parts or accessories?	否 no	
29.4	医疗器械是否有控制接口? Does the medical device have a control interface?	否 no	
29.5	医疗器械是否显示信息? Does the medical device display	否 no	

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序号 Item	影响安全性的特征清单 Lists to identify medical device characteristics that could inpact on safety	特征判定 Characteristics judgment	
	information?		
29.6	医疗器械是否由菜单控制? Is the medical device controlled by a menu?	否 no	
29.7	医疗器械是否用于有特殊需要的人? Will the medical device be used by persons with special needs?	否 no	
29.8	用户接口是否可能使用户开始行动? Can the user interface be used to initiate user actions?	否 no	
30	医疗器械是否使用警报系统? Does the medical device use an alarm system?	否 no	
31	在何种情况下医疗器械可能被有意的误用? In what ways might the medical device deliberately misused?	是 yes	标签不清晰的情况下、说明书提示不清晰的情况下 Label unclear, user manual unclear
32	医疗器械是否保存对患者护理非常重要的数据? Does the medical device hold date critical to patient care?	否 no	
33	医疗器械是否预期用为移动式或便携式? Is the medical device intended to be mobile or portable?	是 yes	便携式 Portable
34	医疗器械的使用取决于其根本性能? Does the use of the medical device depend on essential performance?	是 yes	

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No.	危害 Hard		风险评估 Risk Evaluation				减低风险措施 Risk Reduction Measure	证明 Evidence	NH	ALOR
	总论 General	详细说明可能的危害 Identify hazards	S	O	D	RL				
D2. Energy Hazards 能量危害										
1	电能 Electricity	不适用						非带电产品		
2	冷 Cold	Harm to patient or user	4	2	2	16	Recommendation that use towel to separate the product and skin	非带电产品	无	是
3	机械力 Mechanical force	不适用						非带电产品		
4	离子辐射 Ionizing radiation	不适用						非带电产品		
5	非离子辐射 Non-ionizing radiation	不适用						非带电产品		
6	电磁场 Electromagnetic fields	不适用						非带电产品		
7	可移动部件 Moving parts	不适用						非带电产品		
8	悬浮物 Suspended masses	不适用						非带电产品		
9	支持病人器械失败 Patient support device failure	不适用						非带电产品		
10	压力（管壁破裂） Pressure(vessel rupture)	不适用						非带电产品		
11	声压 Acoustic pressure	不适用						非带电产品		
12	振动 Vibration	不适用						非带电产品		
13	磁场 Magnetic fields(e.g. MRI)	不适用						非带电产品		
D3. Biological hazards 生物危害										
1	微生物污染 Bio-contamination								无	是

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	总论 General	详细说明可能的危害 Identify hazards	S	O	D	RL				
2	生物不相容 Bio-incompatibility	有	4	2	2	16	Incoming material inspection Biocompatibility test report		无	是
3	不正确的成份(化学组成) Incorrect formulation(chemical composition)	Product useless or harm to patient	6	2	2	24	Incoming material inspection, process control	Company test report and record	无	是
4	毒性 Toxicity	无								
5	变态反应性 allergenicity	无								
6	诱变性 mutagenicity	无								
7	致瘤性 oncogenicity	无								
8	致畸性 teratogenicity	无								
9	致癌性 Carcinogenicity	无								
10	再感染，交叉感染 Re-and/or cross-infection	无								
11	致热性 pyrogenicity	有可能					Incoming material inspection, process control			
12	不能保持卫生安全 Inability to m©aintain hygienic safety	无								
13	降解 Degradation	无								

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	总论 General	详细说明可能的危害 Identify hazards	S	O	D	RL				
D4. Environmental hazards and contributory factors 环境危害及其形成因素										
1	电磁场 electromagnetic fields	无								
2	不充足的能量或冷却提供 Inadequate supply of power or coolant	无								
3	对电磁干扰的敏感性 Susceptibility to electromagnetic interference	无								
4	电磁干扰的发射 Emissions of electromagnetic interference	无								
5	不充足的能量提供 Inadequate supply of power	无								
6	不充足的冷却提供 inadequate supply of coolant	无								
7	储存或操作偏离规定的外部环境条件 Storage or operation outside prescribed environmental conditions	Patient therapy effectiveness will be reduced	5	2	2	20	Inform users the correct use method	Instruction for use	无	是
8	与其它器械不相容 Incompatibility with other devices	无								
9	意外的机械危害 Accidental mechanical damage	无								
10	废弃物和/或器械处置的污染	无								

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	总论 General	详细说明可能的危害 Identify hazards	S	O	D	RL				
	Contamination due to waste products and /or device disposal									
D5. Hazards resulting from incorrect output of energy and substances 不正确的能量和物质输出产生的危害										
1	电能 electricity	无								
2	辐射 radiation	无								
3	音量 volume	无								
4	压力 pressure	无								
5	医疗气体的供应 supply of medical gases	无								
6	麻醉剂的供应 supply of anaesthetic agents	无								
D6. Hazards related to the use of the device and contributory factors 使用器械危害及其形成因素										
1	不适当的标签 Inadequate labeling	可能影响储存、搬运、使用。	2	2	2	8	严格按照欧盟指令要求设计标签 Strict accordance with the requirements of the EU directive designed label	使用标签图形符号 产品说明书	无	是
2	不适当的使用手册 Inadequate operating instructions 如: ▪ 附件技术规范不适当 inadequate specification of accessories	Wrong use	5	2	2	20	Customer feedback collection	Instruction for use	无	是

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	总论 General	详细说明可能的危害 Identify hazards	S	O	D	RL				
	▪ 预使用检查规范不适当 inadequate specification of pre-use checks ▪ 操作说明书过于复杂 over-complicated operating instructions ▪ 服务和维修规范不适当 inadequate specification of service and maintenance									
3	由无经验或未经培训的人使用 Use by unskilled/untrained personnel	无								
4	合理的可预见的错误使用 Reasonably foreseeable misuse	烫伤 Scald					在产品说明书上写明使用方法 Stated on the product use instructions			
5	不充分的副作用警告 Insufficient warning of side effects	无								
6	不充分的一次性使用器械重复使用后的可能危害 Inadequate warning of hazards likely with re-use of single use devices	没有热量 No heat	3	2	2	12	告知客户只能一次使用	产品说明书	无	是
7	不正确的测量和其它方面计量 Incorrect measurement and other metrological aspects	无								

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	总论 General	详细说明可能的危害 Identify hazards	S	O	D	RL				
8	与消耗品/附件/其它器械不相容 Incompatibility with consumables/accessories/other devices	无								
9	锐边、锐角 sharp edges or points	无								
C7. Inappropriate, inadequate or over-complicated user interface (man/machine communication) 不正确、不充分或过于复杂的用户介面 （人/机交流）										
1	错误或判断错误 Mistakes and judgement errors	无								
2	重叠和认知检索错误 Lapses and cognitive recall errors	无								
3	滑移和疏忽（精神或实际的）Slips and blunders (mental or physical)	无								
4	违反或偏离说明书、程序等 Violation or abbreviation of instructions, procedures, etc.,	无								
5	复杂或混淆的控制系统 Complex or confusing control system	无								
6	含糊的或不清晰的医疗器械状态 Ambiguous or unclear device state	无								
7	设置、测量或其它信息的含糊或不清晰的显示 Ambiguous or unclear presentation of settings,	无								

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	总论 General	详细说明可能的危害 Identify hazards	S	O	D	RL				
	measurements or other information									
8	结果的错误呈显示 Mispresentation of results	无								
9	视觉、听觉或触觉的不充分 Insufficient visibility, audibility or tactility	无								
10	动作控制或实际状态信息显示的图象不清 Poor mapping of controls to action, or of displayed information to actual state	无								
11	与现存设备相比，模式或图象成问题 Controversial modes or mappings as compared to existing equipment	无								
D8.	**Hazards arising from functional failure, maintenance and ageing 功能性失效，维护、老化的危害和形成因素**									
1	错误的数据转换 Erroneous data transfer	无								
2	维护(包括维修后功能检查技术参数不足)的技术参数不足或缺乏 Lack of , or inadequate specification for maintenance including inadequate specification of post maintenance functional checks	无								
3	不适当的维护 Inadequate maintenance	无								
4	缺乏决定器械寿命的因素决定 Lack of	无								

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	总论 General	详细说明可能的危害 Identify hazards	S	O	D	RL				
	adequate determination of end of device life									
5	缺少电气/机械完整性 Loss of electrical / mechanical integrity	无								
6	不适当的包装(污染和/或器械损坏) Inadequate packaging(contamination and /or deterioration of the device)	Content leakage	5	2	2	20	包装袋寿命验证 Life verify bags	Procedure, Test report	无	是
7	重复使用或不正确的重复使用 re-use and / or Improper re-use	无								
8	由于重复使用使用造成的功能恶化(如液/气路的逐渐闭塞、流阻、电导率的变化) Deterioration in function (e.g. gradual occlusion of fluid/gas path, or change in resistance to flow, electrical conductivity) as a result of repeated use.	无								
B2. Additional hazards to in vitro diagnostic medical devices 体外诊断医疗器械的额外危害										
1	批次的不均匀性、批次和批次的不一致性 Batch inhomogeneity, batch-to-batch inconsistency	无								
2	共同的干扰因素 Common interfering factors	无								
3	延期效应 Carry-over effects	无								

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	总论 General	详细说明可能的危害 Identify hazards	S	O	D	RL				
4	样本标示错误 Specimen identification errors	无								
5	稳定性问题（在储存中、运输中、使用中、容器第一次打开后）Stability problems (in storage, in shipping, in use, after first opening of the container)	无								
6	与样本的抽取、准备及稳定性问题 Problems related to taking, preparation and stability of speciments	无								
7	先决条件的不适当技术规范 Inadequate specification of prerequisites	无								
8	不适当的试验特性） Inadequate test characteristics	无								

生产后信息 Post-production information

生产后经验 Post-production experience:

产品在进料时，控制原材料的材质不能出现错误；生产过程中，注意车间环境的控制；注意控制封口条件的控制；控制产品在储存、运输过程中的保护。

风险管理经验的评审 Review of risk management experience:

控制产品从进料、生产、储存、交货等过程的风险。

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Risk assessment and risk control

NO.	Potential Failure Mode	Potential Effect(s) of Failure	Potential Cause(s)/ Mechanism(s) of Failure	Risk estimation and risk evaluation			Risk Reduction Measure	Evidence	Residual Risk Assessment		
				Severity	Probability	Risk level			Severity	Probability	Risk level
H1	Leaking	Safety concern/Functionality	material preparation	2	3	ACC	Incoming inspection of raw materials based on, KANGDI/WI-07-01	1. Through qualify test , Conform to the requirements 2. Incoming inspection report	2	2	ACC
H2	Leaking	Safety concern/Functionality	1. Chemical in seals 2. Poor seal by production line	2	2	ACC	1.Hourly process review 2.Operator Training	1. Through qualify test , Conform to the requirements 2. DHR 3. PM record/Equipment point inspection record 4. OQ/PQ report 5. Training record	2	1	ACC

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H3	Leaking	**Safety concern/Functionality**	**Consumer abuse**	**2**	**1**	**ACC**	**Instruction for use and symbol on each pack**	**Each pack label**	**2**	**1**	**ACC**
H4	Pack too hot	**Burn**	**Excessive chemicals**	**2**	**2**	**ACC**	**Strengthen the control of mold**	**1. Through qualify test , Conform to the requirements** **2. Mold inspection**	**2**	**1**	**ACC**
H5	Pack too hot	**Burn**	**End user did not use the pack according to Instructions and Warnings**	**2**	**1**	**ACC**	**Instructions and Warnings on each pack**	**1. Through Type test , Conform to the requirements** **2. Each pack label**	**2**	**1**	**ACC**
H6	Pack not hot enough	**Functionality**	**Not enough chemical**	**1**	**2**	**ACC**	**Strengthen the control of mold**	**3. Through qualify test , Conform to the requirements** **4. Mold inspection**	**1**	**1**	**ACC**
H7	Pack not hot enough	**Functionality**	**1. End user did not use the pack according to Instructions and Warnings** **2. Excess expiry date**	**1**	**1**	**ACC**	**1. Instructions and Warnings on each pack** **2. Expiry date on each pack**	**1. Through Type test , Conform to the requirements** **2. Each pack label**	**1**	**1**	**ACC**

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H8	Pre-activation	**Functionality**	**Leakage of inner bag**	**1**	**3**	**ACC**	**1.Inspection of bags to strengthen 2.Verification of the bag 3.Production process checks**	**DHR**	**1**	**2**	**ACC**
H9	Hard to activate	**Functionality**	**Hard to break**	**1**	**2**	**ACC**	**Production process checks every hour**	**1, Through qualify test , Conform to the requirements 2. DHR**	**1**	**1**	**ACC**

All the remaining risk evaluation: take measures to reduce the risks, the risk of harm has been reduced to widely acceptable degree. At the same time to take measures to reduce risk, no new risk.

According the risk estimation table, the risk after control is described as following:

Frequency		Severity Grade			
		4	3	2	1
		Catastrophic	Fatal	Medium	Mild
Frequently	6				
Sometimes	5				

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Occasionally	4				
Seldom	3				
Very Seldom	2			**H1**	H8
Rarely	1			H2, H3,H4, H5	H6,H7,H9

Risk Level	Acceptability（Abbreviation Code）
0～6	Acceptable（ACC）
7～11	As low as reasonably practicable（ALARP）
12～24	Not acceptable（N/ACC）

Conclusion：

We can confirm that, take the action of reduce the risk, it can control the risk of the product, to get the requirement of product safety use:

------According to the intended use or plan and some reasonable finding misuse, confirm what’s hazards will happen.

------In the design, try to use the action of limit and lower the risk of product use, to make the product meets the requirement of safety.

------ Conclusion: After the analysis and evaluation of the hazards, all the remaining risk is acceptable, this product is safe.。

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Informations after sale

	Design changing	Quality problems in the production process	Customer complaints	Recall	Notice	Adverse Event	Maintenance	Legislation
Problem description								
Root cause analysis								
Corrective/Preventive Action:								

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缩略词：Abbreviations used

RE	风险评估 Risk Evaluation
S	严重程度 Severity (9 - 非常严重 very severe, 0 -不严重 not severe)
O	发生频率 Occurrence (9 - 经常 often, 0 - 不发生 never)
D	可发现 Detection (9 - 当风险发生时不可能发现 impossible to detect before risk occurs, 0 - 当风险发生时一定可发现 will be certainly detected before risk occurs)
RL	风险等级 Risk Level = 严重性 Severity × 发生频率 Occurrence × 可发现 Detection 1-9: 可忽略的风险，不需进一步行动 neglectable risk, no further actions; 9-24: 中等风险，建议预防措施 moderate: minimal risk, preventive action recommended; 25-48: 中等风险，要求预防措施 moderate risk, preventive action required; >48: 风险通常一般不可接受 risk is usually not acceptable
RRM	风险减少措施 Risk Reduction Measure
NH	新危害发生 New hazard generated (no/ yes - if yes, 如不可接受，写出危害号码 then number of new hazard indicated)
ALOR	风险是否可接受 Acceptable Level of Risk

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附件 1 风险管理程序

1 Purpose 目的

This standard operating procedure establishes the process for effective risk assessment and risk management for the company's products. 建立有效的风险评估机制与公司产品的风险管理。

2 Scope 范围

This procedure applies to all medical devices manufactured and distributed by Rapid Aid.本规程涉及瑞倍爱生产和经销的所有医疗产品。

3 Procedure 流程

Risk Analysis 风险分析

The Quality Manager, or designate, identifies and documents the intended use or purpose of the medical device. 质量经理或指定人员确定并证明医疗产品的用途。

The Quality Manager, or designate, identifies and records any known or foreseeable hazards complete with an estimate for each hazard.

质量经理或指定人员确定并记录任何已知的或可预见的危害以及危害的评估。

Risk Evaluation 风险评估

Risk acceptability decisions are recorded by the Quality Manager or designate. Where risk reduction is necessary it will be determined, justified and documented. Risk Evaluation is approved by the Quality Manager, or designate. 风险可接受决定有质量经理或指定人员记录。当需要降低风险时，必须经过决定，调节与记录；风险评估由质量经理或指定人员批准。

Risk Control 风险管理

In the event methods are necessary to control risk, the Quality Manager, or designate, will analyze and document options of control. Identified options are evaluated. 风险管理必须采取一定的方法，质量经理或指定人员对管理方法进行分析、评估与确定。

If additional risk controls/reductions are necessary, identification and implementation of each risk control measure is verified and documented. 如果需要采取其他的风险管理降低方法，必须对该方法进行检验与记录。

Risk management documentation ensures all risks are identified and assessed. All risk controls implemented are verified and verification/validation is documented.风险管理文件确保所有的风险得到了确认与评估；所有风险管理方法的实行得到了检验与记录。

Overall residual risk is evaluated and documented. 其它的风险也要评估与记录。

The Quality Manager, or designate, completes the Risk Management Report and retains it as a permanent record in the Medical Device technical and/or design file.质量经理或指定人员编写风险管理报告并作为医疗产品技术资料永久保存。

Post- production risk assessment is monitored through customer complaints, industry or customer feedback, non-conformances and other applicable Quality Systems. If a re-assessment is determined necessary, the Risk Management process will be repeated.通过客户投诉，行业或客户反馈，不合格品和其他适用的质量体系来监控后生产风险评估。

NOTE: Persons performing risk management tasks shall have the knowledge and experience appropriate to the tasks assigned to them. This will include, where appropriate, knowledge and experience of the particular medical device, its intended use and technologies involved or risk management techniques. 注释：负责风险管理任务的人员必须具备相应的知识与经历；这包括具体医疗产品的管理知识、经历和管理能力。

4 Documentation文件

ISO 14791:2007 Medical Devices – Application of risk management to medical devices 医疗产品-医疗产品适用的风险管理
Failure Modes and Effects Analysis (FMEA)失效模式与有效分析

标准代号 Standards No.	标准英文名称 In English Description	标准中文名称 In Chinese Description
QB/HENGDA-001-2012	Heat pads Company Standards	暖贴产品企业标准
EN ISO 15223-1-2012	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	医疗器械.用于医疗器械标签、作标记和提供信息的符号.通用要求
EN ISO 13485:2012	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2012) EN ISO 13485:2012/AC:2012	医疗设备.质量管理体系.管理要求
EN ISO 14155-1:2011	Clinical investigation of medical devices for human subjects - Part 1: General requirements (ISO 14155-1:2003)	以人为对象的医疗器械的临床调查--良好临床规程
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices (ISO 14971:2012)	医疗器械 风险管理的应用
IEC62366	Medical devices - Application of usability engineering to medical devices	医疗器械-可用性工程对医疗器械的应用
ISO10993-5:2009	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity	医疗器械的生物学评价--第5部分：体外细胞毒性试验
ISO 10993-10:2010	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization	医疗器械的生物学评价--第10部分：刺激和皮肤敏化试验

临床评估报告

Clinical assessment report

产品名称：暖贴

Product name：Heat Pads

公司名称：河南核信恒达实业有限公司

Company name: Henan Hexin Industrial Co., Ltd.

编制/Draft/ Date：

复核/ Reviewed By/ Date:

批准/ Approved By/ Date：

1、临床评估综述 clinical assessment review

1.1 临床评价标准依据:basis of clinical evaluation standards

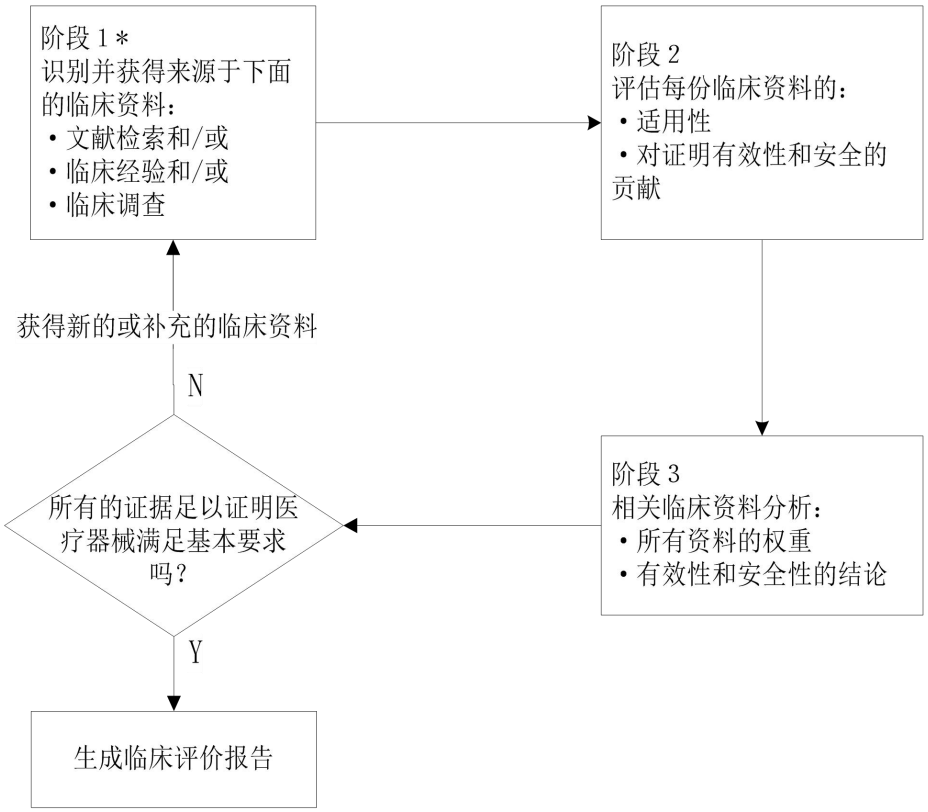
按照 MEDDEV.2.7.1 医疗器械临床评价指南

according to MEDDEV.2.7.1 medical devices clinical evaluation guideline

1.2 临床评价阶段概述 clinical evaluation phase review

临床评价阶段按照以下流程图划分并进行临床评价：

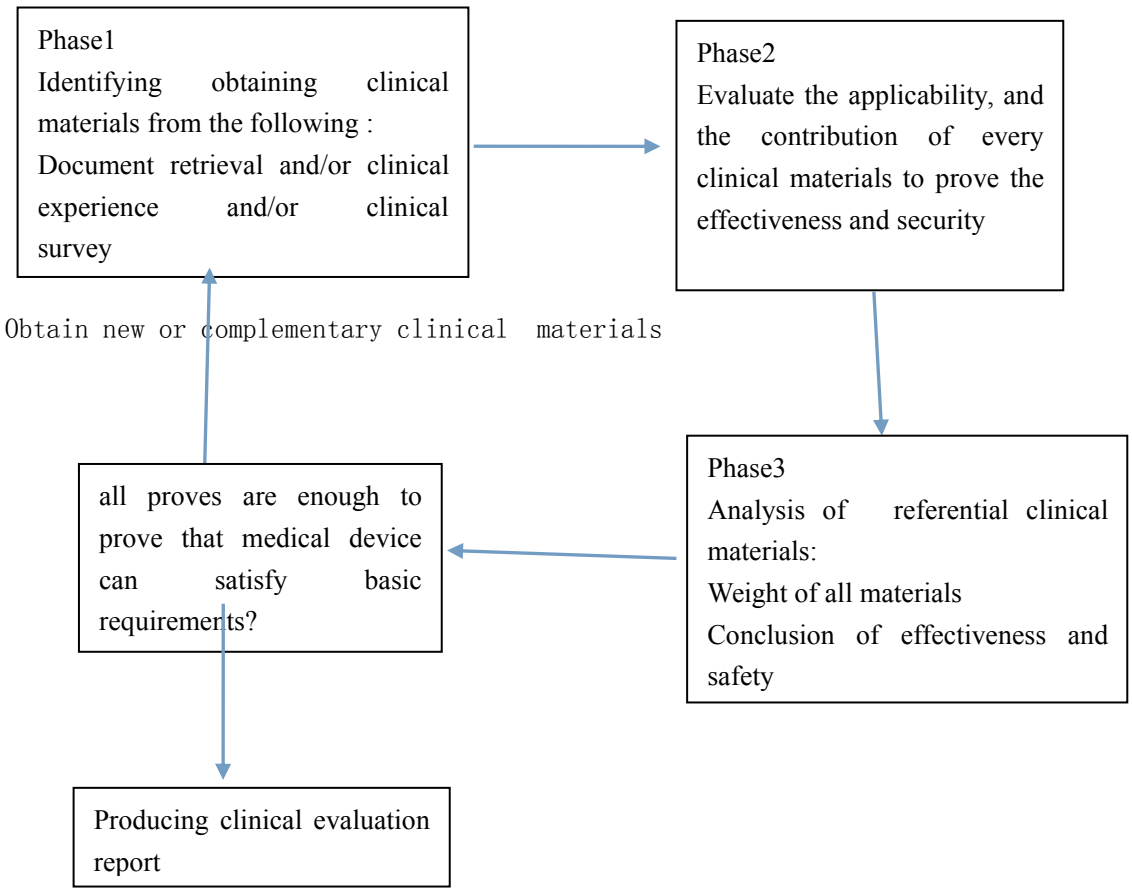
In clinical evaluation phase, clinical evaluation is done according to the flowing chart below :



*符合协调标准的要求可以认为能充分满足相关的基本要求

图 1：临床评价流程图

figure1:flowing chart clinical evaluation



1.3 临床评估数据的来源：source of clinical assessment data

根据 MEDDEV.2.7.1 医疗器械临床评价指南，依据临床数据来源的不同，临床评估数据有三种路径：

According to MEDDEV.2.7.1 medical devices clinical evaluation guideline , and the different sources of clinical assessment data, clinical assessment CAN BE GOT through three paths.

1.3.1 来之文献的数据（见 MEDDEV.2.7.1 医疗器械临床评价指南 6.1）：

Data from literature(refer to MEDDEV.2.7.1 medical devices clinical evaluation guideline 6.1)

例如：For example:

a) 公认的科学出版物包括期刊和书籍; Accepted scientific publications including periodicals and books.

b) 出名的的公共网站和网站的其他制造商；well known public websites and other manufactures

c) 未发表的文件也会被列入考虑的范畴。Unpublished documents also be considered

d) 第三方完成的针对目标器械的临床调查报告 clinical survey report aimed at target devices by third party

e) 第三方完成的针对等同器械的临床调查报告 clinical survey report targets equivalent equipment by third party

f) 第三方完成的目标器械的不良事件报告 adverse report of target equipment by third party

g) 第三方完成的等同器械的不良事件报告 adverse report of equivalent target equipment by third party

1.3.1.1 **文献检索的范围 the scope of literature retrieval**

涵盖产品的安全，性能及不良事件等信息的文献

Literature covering safety, performance, adverse events and other information of productions

1.3.1.2 文献检索的方法 ways of literature retrieval

(i) 文献检索日期：2014 年 05 月 10 日 date of literature retrieval: May 10th,2014

(ii) 文献检索人员：Xie BaoZhen member of literature retrieval:Xie BaoZhen

(iii) 检索涵盖的时期范围：近 20 年关于产品的安全、性能及不良事件信息、科学文献。

Period of literature retrieval: scientific literature about the safety,performance, adverse events and other information of the products in the past 20 years.

(iv) 资料的文献来源：literature resource of materials

- 国家 SFDA 网站 national website SFDA
- 万方数据库 Wanfang database
- 维普数据库 vip database
- 不良事件报告资料库(比如 MAUDE, IRIS)data bank of adverse events (such as MAUDE, IRIS)
- 美国 FDA 网站 American website FDA
- 本产品的安全测试报告。The safety test report of the products

- 产品国内 SFDA 认可的临床试验基地出具的临床试验报告 clinical trial report issued by clinical sites and approved by SFDA

(v) 资料库检索细节：details of data bank retrieval

- 检索关键字：key words

注：如以上关键字检索文件效果不好，应以“冷暖贴 临床”为主要关键字，并依据临床评价范围对检索到的文献与进行初步筛选。

Notice: if the retrieval effect of the above key words are not well, “cooling or warmer patch clinical”should be used as key words. In addition, the retrieved literature should be screened according to clinical evaluation scope.

- 所使用的媒介：电脑网络。

Medium :computer network

(vi) 资料的选择标准：依据文献的内容与临床评价范围相关性进行初步筛选。

Selection criteria of materials: screened preliminary according to the correlation of literature contents and clinical evaluation scope

1.3.1.3 文献检索的输出 literature retrieval output

见 4.1-4.8 refer to 4.1-4.8

1.3.2 来之临床经验的数据（见 MEDDEV.2.7.1 医疗器械临床评价指南 6.2）data from clinical experience (refer to MEDDEV.2.7.1 medical devices clinical evaluation guideline 6.2)

例如：for example:

制造商完成的上市后监督报告；posted-listed monitoring report completed by manufacturer

制造商完成的注册研究；registry investigation by manufacturer

制造商完成的队列研究（可能含有未公布的长期安全性和性能数据）cohort studies completed by manufacturer(may include unpublished long-term data of safety and performance.

不良事件数据（由制造商或主管当局掌控）adverse events data(controlled by manufacturers or the authorities)

目标器械上市前来之慈善应用项目中的个体患者的数据临床相关领域的纠正措施的细节（召回、忠告性通知、风险警告）；

Details of corrective measure in clinically relevant field(recall,advisory notice,risk warning)

1.3.3 来之临床调查的数据（见 MEDDEV.2.7.1 医疗器械临床评价指南 6.3）

Data from clinical survey (refer to MEDDEV.2.7.1 medical devices clinical evaluation guideline 6.3)

以制造商名义开展的临床调查（ENISO14155 标准的第 1 部分和第 2 部分）

Clinical survey started in the name of manufacturer(the first and second part of ENISO14155)

科学文献中报告的临床调查数据；

Clinical survey data from scientific literature report

1.3.4 临床数据的使用方法 method of application of clinical data

(i) 附上引用临床数据的复印件；enclosed with copies of clinical data quotation

(ii) 资料选择过程；materials election process

(iii) 附上流程图相关表格，以说明引用资料如何被评价并作为临床评价资料；

Enclosed with flowing chart and relevant table to illustrate how the cited materials be assessed and be regarded as clinical evaluation materials.

1.3.4.1 临床数据的适宜性评价 suitability evaluation of clinical data

基于对产品拟评价的内容及文献检索协议，通过流程 1 及表格 C1 对检索到的文件进行初步适宜性识别。Preliminary Identify the retrieved documents through process1 and table C1, based on literature retrieval agreement and draft evaluation to the products.

临床数据适宜性判定标准 standard of clinical data suitability

适宜性标准 Suitability standard	描　　述 description	分级体系 classification system
恰当的器械 proper equipment	资料是从拟评价器械生成的吗 materials produced from draft evaluation of equipment?	□D1 实际器械 actual equipment □D2 相等器械 equivalent equipment □D3 其他器械 other equipment
恰当的器械应用 Proper application of equipment	器械的预期用途相同吗？（比如调节方法，应用等）does the equipment have the same function as expected ？	□A1 同种用途 same function □A2 细微差别 minor difference □A3 很大差别 great difference
恰当的患者群 Proper patient group	采集数据的患者群代表预期应用人群（比如年龄，性别等）及医用环境（比如疾病包括状态和严重度）吗？Is the collected patient group represents the expected applicable group(such as age,gender) and medical environment(such as the state and severity of the disease)s ？	□P1 适用 applicable □P2 部分适用 partly applicable □P3 不同 different
选用报告/数据整理 Selected report/data clearing up	报告或资料包括足够的信息从而进行理性和客观的评价吗 does report or materials cover enough information to do rational and objective evaluation?	□R1 高质量 high quality □R2 少量缺陷 minor defects □R3 信息不足 deficient information

表 1：临床数据适宜性判定表　table 1 :decision table of clinical data suitability

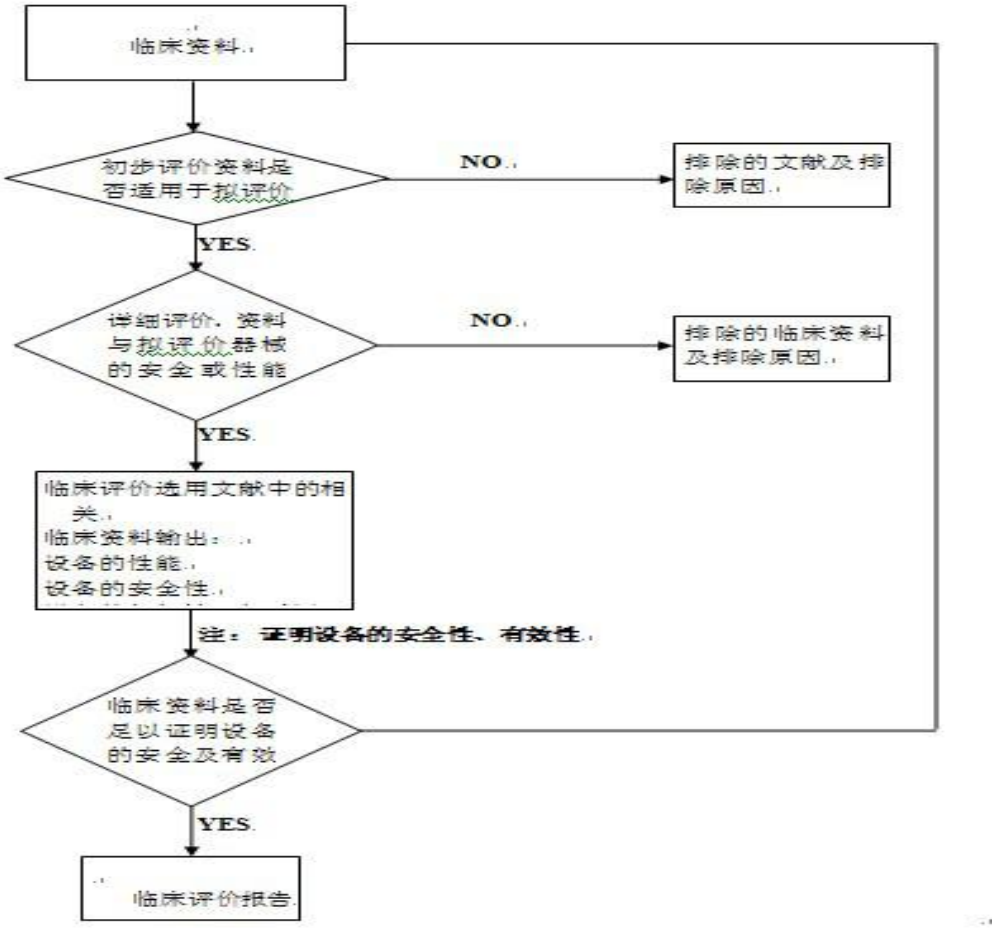


图 2 临床数据适宜性判别流程 figure 2 identifying process of clinical data suitability

1.3.4.2 临床数据贡献判定标准：criterion of clinical data contribution

数据贡献准则 data contribution principle	描　　述 description	分级体系 classification system
数据源类型 type of data resources	研究的方法是否恰当？ Is the research method appropriate?	□T1 是 yes □T2 否 no
结果衡量 measure the result	报告的结果反映了产品的预期性能吗？ Does the result reflect the expected performance of the products?	□01 是 yes □02 否 no
统计意义 Significance of statistics significance	进行统计分析了吗？统计分析是否恰当 Have done statistics and analysis? Is the statistics and analysis appropriate?	□S1 是 yes □S2 否 no
临床意义 clinical significance	治疗效果临床观察的意义重要吗？Are therapeutic effect and clinical observation important?	□C1 是 yes □C2 否 no

表 2：临床数据贡献率判定标准 table 2: criterion of contribution rate of clinical data

2、器械及预期用途描述 description of equipment and expected function

2.1 产品名称及制造商 name of products and manufacturer

产品名称：暖贴 name of product : warmer pad

制造商：河南康迪药械有限公司 manufacturer: Henan Kangdi Medical Devices com.,ltd.

2.2 热敷的机理 mechanism of hot compress

热敷时皮肤毛细血管扩张，血液循环加快，在热刺激及能量渗透作用下，人体表层细胞蛋白分解产生类组胺物质并被血液带至全身使组织营养再生机能增强，促进健康恢复。引用之《基础护理学》“第九章 冷、热疗法”

when do hot compress, skin capillary expand, blood circulation speed up .due to thermal stimulus and energy penetration, cellular protein of human body surface disintegrate to produce substances like histamine that are taken to other party of human body to enhance the nutrition-regenerative mechanism of tissue,so that to improve human health.the above is quoted from “chapter 9 temperature therapy” of *Fundamental Nursing*

暖贴工作原理：暖贴的反应原理为利用原电池加快氧化反应速度，将化学能转变为热能

Operating theory of warmer pad: accelerate oxidization by using primary battery to transfer chemical energy to heat energy

负极 negative pole ：Fe-2e-=Fe2+

正极 positive pole：O2 + 2H2O + 4e-=4OH-

总反应 overall reaction：2Fe + O2 + 2H2O=2Fe(OH)2

4Fe(OH)2 + 2H2O + O2=4Fe(OH)3↓2Fe(OH)3 ==== Fe2O3+3H2O

产品通过大量试验后，找出最佳原材料比例，确保产品处于安全热敷的温度。

After large amounts of experiments, find out the proportion of best raw materials to ensure the product in safe temperature when do hot compress.

2.3 器械的工艺背景 technology background of equipment

为了提高产品的可靠性、安全性和便携性，我公司生产了一次性暖贴用来满足客户的需求。

我公司生产的暖贴有取暖、热疗的功效。

我公司生产的暖贴不需要借助外界能量，撕开外袋，便可在任何的环境下发热，这个功能大大提高了便携性，在不便于用外界能源加热的情况下，我公司产品可以发挥其独到的作用。

由于我公司产品不需要每次借助外界能源就可以发热，这便可以通过在研发阶段大量实验，找出化学物品的最佳比例，然后按此比例进行生产，大大提高了产品性能的稳定性，不容易受外界能源的波动而发生温度大幅度的波动，提高了产品的稳定性，从而提高了产品的质量、安全性和可靠性。

我公司生产的暖贴便携性比热水袋好，是热水袋的升级产品，可以达到热水袋的预期用途，

To improve the reliability,safety, portability, we produce disposable warmer pad to meet requirements of customers.

Our warmer pads have the function of heating and heating therapy.

Our warmer pads do not rely on outside energy.after being taken out from the bags , they can give out heat in any environment. This function improves the portability. when outside energies are not available,advantages our warmer pads have more advantages.

As our warmer pad can give out heat without depending outside energy resources, a large amount of experiments can be done in the phase of research and development to find out the best ratio of ingredient. Produced under the best ratio,together with its characteristics, our warmer pad has higher stability,therefore higher quality, safety,and reliability.

Our warmer pad ,which is the upgraded product of hot-water bag, has higher portability than hot-water bag and can reach the expected function of hot-water bag.

2.4 器械的预期用途 Expected function of equipment

可用于热疗、取暖等用途。It can be used to do thermal therapy and heating

一次性使用，非侵入型医疗器械，不与人体直接接触（与毛巾配合使用）

凡是用 36℃-45℃进行热敷，均具有一定的热疗功效，具体使用方法，由医生根据需要选择，关于热敷的基本知识可以参考《基础护理学》主编 尚少梅 李小寒 人民卫生出版社 第九章 冷、热疗法。

凡是用 36℃-45℃进行热敷，均具有取暖功能。

It can be used to do thermal therapy and heating.

It is disposable and non-invasive medical device. Never put it directly to skin.(use it with towel)

Hot compress under 36℃-45℃ has thermal therapy. For using method, doctor can choose according to specific need. For basic knowledge,please refer to “Chapter nine cooling or thermal therapy ”of *Fundamental Nursing* (Chief editor:Shang Shaomei , Li Xiaohao People’s Medical Publishing Press)

Hot compress under 36℃-45℃ has heating function.

2.5 器械结构及组成：structure and composition of equipment

产品由内袋、外袋、化学品组成。The product is composed of inside bag, outside bag and chemicals.

2.6 器械的临床性能声明 statement of clinical performance of equipment

特此声明我公司生产的暖贴具有取暖、热疗功效。产品使用温度范围为 36℃-45℃。

We hereby declare that our warmer pads can be used to do heating and thermal therapy.It is used in the rang of 36℃-45℃。

2.7 器械的安全性能声明 safety statement of equipment

我公司生产的暖贴不能直接使用，需要使用者用毛巾进行包裹使用，最高温度为 65℃，包裹后，毛巾的温度范围在 45℃之内，加毛巾后，产品的使用温度将在安全使用温度范围内。

Our warmer pad can’t be directly out on the skin. It should be used wrapped up with towel.the highest temperature of our product is 65℃. When wrapped up with towel,the temperature of the towel is under 45℃.wrapped up with towel, the warmer pad can work under safe temperature range.

2.8 关于材料的安全性分析 safety analysis of the materials.

我公司生产的暖贴不与皮肤直接接触

铁粉、蛭石粉、活性炭、盐均为无毒化学品，可查相关知识。

Our warmer pad can ‘t directly touch the skin.

Iron powder, vermiculite,activated carbon are salt are all non-toxic chemicals.

2.9 灭菌性 Sterilization

暖贴不需要灭菌 sterilization is not needed.

3 临床数据类型的选择及评估的背景 election of clinical data type and evaluation background.

3.1 医疗器械的开发背景 developing background of medical devices

该医疗器械是面向便携性和面向安全性的设计，是在其它类型的暖贴的改进产品，例如和热水袋相比，大大提高了便携性和安全性：产品不需要借助外部能源即可发热，产品的温度范围是经过严格的试验而设计的，故产品的温度稳定，产品的稳定性更好，对用户更安全，不易于烫伤，烫伤的可能性比热水袋大大降低。

该原理产品目前已在上市产品中有了，原理是比较成熟的。

This medical device, geared to portability and safety,is a upgraded product based on other kinds of warmer pads. Compared with hot-water bag, it has higher portability and safety. As it can give out heat without depending outside energy ,and it has gone through strict temperature test, it is more stable and safer hot-water bag.

This kind of product in among listed products. The theory is mature at present.

3.2 选择的临床数据类型 type of clinical data

根据“MEDDEV.2.7.1 医疗器械临床评价指南”有 3 种类型的数据可供做临床评估，由于我公司的产品为低风险设备，根据“MEDDEV.2.7.1 医疗器械临床评价指南中 6.2”科学文献或临床调查报告较少，所以我们选择采用“MEDDEV.2.7.1 医疗器械临床评价指南中 6.1+6.2”的评估方式。

实际的临床数据类型的选择执行本临床评估报告的 1.3.1 和 1.3.2。

according to MEDDEV.2.7.1 medical devices clinical evaluation guideline, there are 3 kinds of data that can be used to do clinical evaluation. Due to the low risk of our product,there are less reports and literature according to MEDDEV.2.7.1 medical devices clinical evaluation guideline 6.2. As a result, we use the assessment method in MEDDEV.2.7.1 medical devices clinical

evaluation guideline 6.1+6.2.

The election of clinical data type is done according to the 1.3.1 and 1.3.2 of this clinical evaluation report.

4 临床数据分析 analysis pf clinical data

4.1《建筑环境学》（第二版）朱颖心/主编 中国建筑工业出版社 *Architect environmentology(second edition) Zhu Yingxin/chief editor China Building Industry Press*

4.1.1 该文献的适用性分析：该教材为中国最权威的大学，清华大学朱颖心教授编著权威性毋庸置疑，该书中描述了人体皮肤温度与人体感觉的关系，该结论是具有普遍性的结论，不是特定条件下的结论。从表中可以看出，35 摄氏度人开始有热的感觉，到 45 摄氏度以上皮肤组织在 20 分钟内会被烫伤，见图 3 和表 4. 而热敷的时间一般为 15-30 分钟，所以需要根据表 3、图 3、表 4 找出 20 分钟内不会被烫伤的温度范围。

Applicability analysis of the literature: this book is written by professor Zhu Xinying of Tsinghua University which is the most famous university in China. Therefore, its authority is undisputed. In this book, the relation between human feeling and the temperature of human skin. The conclusion is universal, not reached under specific condition. It can be seen from the table that people will feel hot when the temperature reach 35℃.when the temperature stays above 45℃ for more than 20 minutes, human skin tissue will be scalded(refer to table3 and table4).As hot compress time last 15-30 minutes, safe temperature range that can ensure the skin can’t be scalded in 20 minutes needed to be fined out according to table3,figure3,table4.

皮肤温度	状　态
45℃ 以上	皮肤组织迅速损伤，热痛阈
43~41 ℃	被烫伤的疼痛感
41~39 ℃	疼感域
39~37 ℃	热的感觉
37~35 ℃	开始有热的感觉
34~33 ℃	休息时处于热中性状态， 热舒适
33~32 ℃	中等(2-4met)运动量时感觉舒适
32~30 ℃	较大(3-6met)运动量时感觉舒适
31~29 ℃	坐着时有不愉快的冷感
25℃ (局部)	皮肤丧失感觉
20 ℃(手)	非常不快的冷感觉
15 ℃(手)	极端不快的冷感觉
5 ℃(手)	伴随疼感的冷感觉

表 3：皮肤温度与皮肤感受状态对应表 table3: corresponding table of skin temperature and skin feeling

该表格结论与“水温-触水时间对应表”以及“烫伤温度与接触时间的对应表”完全兼容

The conclusion of the table completely match with the “water temperature-time of touching water corresponding table”and “scalding temperature-time of touching corresponding time”

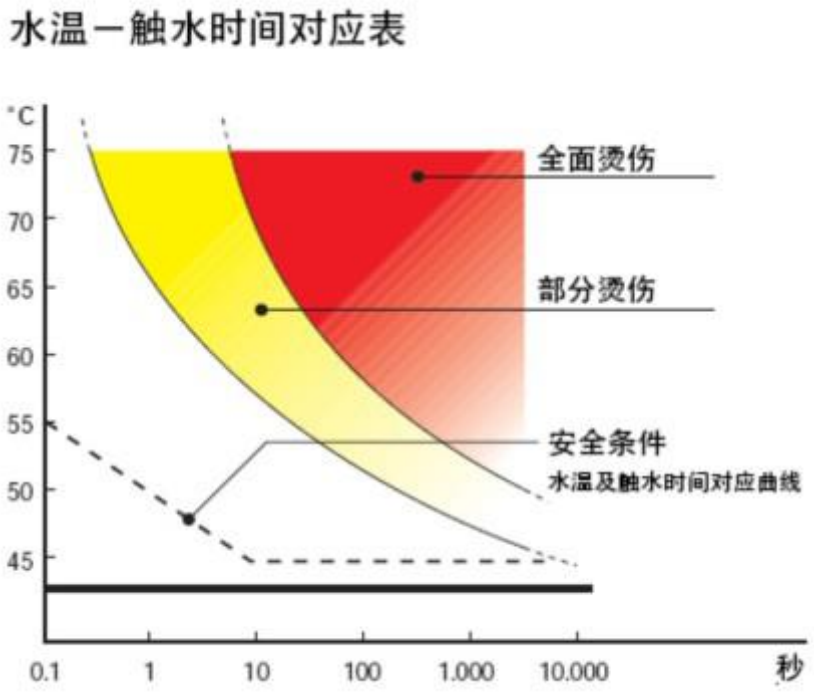


图 3：水温与触水时间对应图

figure3: water temperature-time of touching water corresponding table

水 温	成年人	0-5岁儿童
70℃	1 秒	--
65℃	2 秒	0.5 秒
60℃	5 秒	1 秒
55℃	30 秒	10 秒
50℃	5 分	2.5 分

表 4：烫伤温度与接触时间的对应表

figure4:scalding temperature-time of touching corresponding time

4.1.2 该数据对证明我公司产品安全性的意义：根据图 3，当温度为 45 度以下时，安全时间为 10000 秒，即大概为 166 分钟不被烫伤，所以低于 45 度以下的温度足够安全，从表 3、图 3、表 4 可以看出热敷超过 20 分钟的安全温度为 35℃-45℃之间，只要通过实验证明我公司产品实际使用的温度的温度不超过 45℃，即可证明我公司的产品是安全的。

The significance of the data to prove the safety of our products: according to figure 3, when the temperature is under 45℃, the safety time is 10000seconds, meaning that during about 166 minutes, one can't be scalded. So temperature below 45℃ is safe enough.From table 3,figure3 and table 4, it can be seen that the safe temperature is in 35℃-45℃ within 20 minutes.as long as our product can be proved under 45℃ when be used,it can be said safe.

4.1.3 该数据对证明我公司产品有效性的意义：人体温度为 37℃，根据《基础护理学》主编 尚少梅 李小寒 人民卫生出版社 第九章 冷、热疗法第三节中对热敷的定义“热疗法是用高于人体温度的物质，作用于机体的局部或全身，以达到促进血液循环、消炎、解痉和舒适的治疗方法。” 从这个概念不难看出，只要暖贴的温度可以达到高于人体的温度，就可以起到热敷的功效，从而证明产品是有效的。而大量试验证明我公司的产品温度是可以高于人体温度的，从而也就证明了我公司产品是有热敷功效的。

The significance of the data to prove the effectiveness of our products: human temperature is 37℃. According to the definition given in the section III of Chapter Nine cooling or thermal therapy ”of *Fundamental Nursing* (Chief editor:Shang Shaomei , Li Xiaohao People's Medical Publishing Press), “thermal therapy refers to the method to use substances having higher temperature on human body so that to accelerate blood circulation,diminish inflammation,spasmolysis”. It is easy to see from the conception that the warmer pad can have hot compress effect as long as it reaches the temperature higher than human body. And amounts of experiments have proved that our warmer pad can reach the temperature higher than human body, which proves that our warmer pad has the effect of hot compress.

4.2 建筑环境学　胡平放/主编 华中科技大学出版社

Architect environmentology(second edition)　Hu Pingfang/chief editor HuaZhong University of Science and Technology *Press.*

4.2.1 该文献的适用性：该书为中国知名大学“华中科技大学”编著，书中第 3 章 人体对热湿环境的反应，也有同样的论述。具体看 4.1.1

The suitability of the literature: edited by Chinese famous university HuaZhong University of Science and Technology.in chapter 3 of the book,there is the same discourse about human body reaction to temperature.For specific knowledge, please refer to 4.1.1

4.2.2 该数据对证明我公司产品安全性的意义：同 4.1.2

The significance of the data to prove the safety of our products,ditto 4.1.2.

4.2.3 该数据对证明我公司产品有效性的意义：同 4.1.3

The significance of the data to prove the effectiveness of our products,ditto 4.1.3.

4.3 建筑环境学　杨晚生/主编 华中科技大学出版社

Architect environmentology Yang Wansheng/chief editor HuaZhong University of Science and Technology *Press.*

4.3.1 该书为中国知名大学“华中科技大学”编著，书中第 3 章 人体对热湿环境的反应，也有同样的论述。

Edited by Chinese famous university HuaZhong University of Science and Technology.In chapter 3 of the book,there is the same discourse about human body reaction to temperature.

4.3.2 该数据对证明我公司产品安全性的意义：同 4.1.2

The significance of the data to prove the safety of our products,ditto 4.3.2.

4.3.3 该数据对证明我公司产品有效性的意义：同 4.1.3

The significance of the data to prove the effectiveness of our products,ditto 4.1.3.

4.4 建筑环境学　黄晨/主编 机械工业出版社

Architect environmentology　Huang Chen/chief editor　Machine Industry Press

4.3.1 该书为中第 3 章 人体对热湿环境的反应，也有同样的论述。

In chapter 3 of the book,there is the same discourse about human body reaction to temperature.

4.4.2 该数据对证明我公司产品安全性的意义：同 4.1.2

The significance of the data to prove the safety of our products,ditto 4.1.2.

4.4.3 该数据对证明我公司产品有效性的意义：同 4.1.3

The significance of the data to prove the effectiveness of our products,ditto 4.1.3.

4.5 文献：温度与皮肤烫伤的关系

Literature: relation between temperature and scald

摘要：人体皮肤温觉的温度为 20℃—47℃之间，当温度在 35℃左右，人体皮肤产生温觉；使用温度超过 45℃时，产生热甚至烫的感觉；使用温度达到 47℃时，有烫伤痛感；温度大于 50℃时就会烫伤形成水疱；如果 60℃接触人体皮肤一分钟，就会造成III度烫伤。

Abstract: the skin temperature of human range from 20℃ to 47℃. When the temperature is about 35℃,people can feel the heat.If above 45℃, one will feel hot or even feel burned. If it reaches 47℃ ,one will feel scalded. When it is above 50℃, the skin will be scalded to produce blister.And if the temperature is 60℃, the skin will suffer III degree scald for one minute touching,

4.5.1 文献的适用性：该文献的结论与文献 4.1 的结论完全相符。并且在很多知名医院主治医生的诊治过程中大量使用，在我国前一段时间发生的一起事故“婴儿培养箱烧伤婴儿”的事件分析中也引用了此结论，故这一结论目前已被书籍使用，并以使用于临床治疗和分析。

Applicability of literature: the conclusion of the literature agrees with that of literature 4.1. And it is used by many attending doctor many famous hospital.This conclusion is also cited in the analysis of the event “infant incubator scalds infant to death”.Therefore this conclusion has been used in many books, and been used in clinical analysis and treatment.
见“婴儿培养箱烧伤婴儿分析报告“：三问“医院烤死婴儿”：暖箱温度何以致人烫伤
http://health.sohu.com/20130719/n382019754.shtml

Refer to “analysis report of infant incubator scalds infant to death”: three “why” for hospital scald infant to death:how can warmer box scald people”.http://health.sohu.com/20130719/n382019754.shtml

4.5.2 文献对证明我公司暖贴安全性的意义：该结论同样说明了温度低于 45℃产品安全。

The significance of the literature to prove the safety of our warmer pad: the conclusion also shows the safety of the products below 45℃.

4.5.3 文献对证明我公司产品有效性的意义：该结论说明，只要产品温度可以达到在 35℃—45℃之间使用，就可以证明产品是安全有效的，人体温度为 37℃，根据《基础护理学》主编 尚少梅 李小寒 人民卫生出版社 第九章 冷、热疗法第三节中对热敷的定义“热疗法是用高于人体温度的物质，作用于机体的局部或全身，以达到促进血液循环、消炎、解痉和舒适的治疗方法。”从这个概念不难看出，只要暖贴的温度可以达到高于人体的温度，就可以起到热敷的功效，从而证明产品是有效的。而大量试验证明我公司的产品温度是可以高于人体温度的，从而也就证明了我公司产品是有热敷功效的。

The significance of the literature to prove the effectiveness of our products: this conclusion shows that as long as the temperature of the product is in 35℃—45℃, it is safe and effective to human body. Human temperature is 37℃. According to the definition given in the section III of Chapter Nine cooling or thermal therapy ”of *Fundamental Nursing* (Chief editor:Shang Shaomei , Li Xiaohao People’s Medical Publishing Press), “thermal therapy refers to the method to use substances having higher temperature on human body so that to accelerate blood circulation,diminish inflammation,spasmolysis”. It is easy to see from the conception that the warmer pad can have hot compress effect as long as it reaches the temperature higher than human body. And amounts of experiments have proved that our warmer pad can reach the temperature higher than human body, which proves that our warmer pad has the effect of hot compress.

4.6 大量知名医院的主治医生引用《建筑环境学》中温度与皮肤烫伤的关系

Many attending doctor of well-known hospitals cites from the *Architect environmentology* the relation between temperature and skin scald.

4.6.1 大量知名医生主要引用的结论：人体皮肤温觉的温度为 20℃—47℃之间，当温度在 35℃左右，人体皮肤产生温觉；使用温度超过 45℃时，产生热甚至烫的感觉；使用温度达到 47℃时，有烫伤痛感；温度大于 50℃时就会烫伤形成水疱；如果 60℃接触人体皮肤一分钟，就会造成III度烫伤。

Conclusion cited by many well-known doctors: thalpotic temperature of human skin is in 20℃—47℃. When the temperature is about 35℃,people can feel the heat.If above 45℃, one will feel hot or even feel burned. If it reaches 47℃ ,one will feel scalded. When it is above 50℃, the skin will be scalded to produce blister.And if the temperature is 60℃, the skin will suffer III degree scald for one minute touching,

4.6.2 引用证据 cited evident

三问“医院烤死婴儿”：暖箱温度何以致人烫伤

“hospital scald infant to death:how can warmer box scald people”

http://health.sohu.com/20130719/n382019754.shtml

通常水温达到多少度时会烫伤人体皮肤？What temperature of water can make humane skin scalded ?

http://zhidao.baidu.com/link?url=TV6i694eBm9--NTbV7ytlYXMPjpAHT1QXMR3Pvlam8_hxiNy2LD2KjLcZ2C1B_V1drl1uXEhJV52rE9lTsGqJa

在多少度水温才属于烫伤呢 In what temperature do does skin wounds are regarded as scald?

http://www.haodf.com/wenda/shaoshangkangfu_g_655608187.htm

对人体来说怎样才算烫 how can be regarded as scald?

http://zhidao.baidu.com/link?url=GrKSBnqPntze-ul_HxVPG773fIKmrrfnP3emVezmVezqpLE-ApP9ZLsdiFVNjFXPhIf5In-0UwROTHIb8qxg-q

关于高温的定义 definition of temperature

http://bbs.anquan.com.cn/thread-208591-1-1.html

4.6.3 该结论适用性分析：同 4.5.1

Applicability analysis of the conclusion,ditto 4.5.1

4.6.4 该结论对对证明我公司产品安全性的意义：同 4.5.2

The significance of the conclusion to prove the safety of our products,ditto 4.5.2.

4.6.5 对证明我公司产品有效性的意义：同 4.5.3

The significance to prove the effectiveness of our products, ditto 4.5.3

4.7 产品使用说明书对产品安全性与有效性的证明 s

Specifications proving the safety and effectiveness of our products.

4.7.1 产品说明书暖贴安全性的意义：公司的产品说明书通过注意事项、警告描述保证了客户正确的使用产品，从而确保了产品使用过程中的安全性。

The significance to put the safety of warmer pad in specifications: the specifications ensure the customers to use the products in the right way through notices and warning. This ensure the security in using process.

4.7.2 产品说明书暖贴有效性的意义：

The significance to illustrate the effectiveness of warmer pad in specifications:

产品说明书对暖贴的有效期、产品的使用注意事项等进行了描述，确保了客户的有效使用，从而保证产品使用过程中的有效性。

The product specifications ensure the customers to use the product effectively by providing validity of products and notices when using them.This ensure the effectiveness of the products.

4.8 产品标识对产品安全性与有效性的证明

Products marking proving the safety and effectiveness of our products.

4.8.1 产品标识暖贴安全性的意义：公司的标识通过警示标识、安全说明保证了客户正确的使用产品，从而确保了产品使用过程中的安全性。

The significance of products marking to the safety of warmer pad: the products marking ensure the customer to use the products properly through warning marking and safety instruction.this ensure the safety when use the them.

4.8.2 产品说明书暖贴有效性的意义：

The significance of products specifications to the effectiveness of warmer pad:

产品标识对暖贴的使用注意事项等进行了描述，确保了客户的有效使用，从而保证产品使用过程中的有效性。

The products marking ensure the customer to use the products properly through providing notices .This ensure the safety when use the them.

5 **资料贡献率评价** evaluation of materials contribution rate

拟评价内容 the draft evaluation content	**引用文献** Literature cited	**数据源** Data source	**描述** description	**分级体系** Classification system	**结论** conclusion	**证明材料** Referential materials
5.1 产品风险及潜在风险评价 Risk of products and potential risk evaluation	风险管理报告 risk management report	医疗器械的特点 产品生命周期分析 The characteristics of medical devices and LCA	资料是从拟评价器械生成的吗 Is the materials produced from the draft assessment equipment?	■ D1 拟评价器械 draft evaluation equipment ☐D2 等同器械 equivalent equipment ☐D3 其他 other	暖贴的所有风险都是可控的 All risks of warmer pad are controllable 暖贴的受益是大于风险的 Benefits overweight risks	见 CE-01-10 中 12 风险分析报告 refer to the 12 risk analysis report in CE-01-10

5.2 资料适宜性评价 Suitability evaluation of materials	清华大学文献 相关专业杂志 Literature of Tsinghua University Relevant magazine	相关科学实验 relevant scientific experiment	器械的预期用途相同吗？Is the expected function the same ?	■A1 预期用途相同 same □ A2 轻微偏差 minor difference □ A3 重大偏差 major difference	热敷的有效温度为 35℃-45℃之间，只要通过实验证明我公司产品的温度在这个温度范围内，即可证明我公司的产品是有效的，达到了取暖和热敷的预期用途 we know that the effective temperature of hot compress ranges from 35 ℃ -45 ℃ . Therefore our product can be proved to be effective and has the function of heating and hot compress if the temperature of our product can be proved in the range	见建筑环境学 胡平放/主编 华中科技大学出版社 Refer to architect environmentology (Hu Pingfang/chief editor HuanZhong University of Science and Technology Press

					through experiment.	
5.3 产品安全性评价 Safety evaluation	a、产品温度测试报告 temperature test report b、产品临床经验温度数据 temperature data from clinical experience c、相关文献给出的安全温度范围 safe	相关科学实验 Relevant scientific experiment 相关权威专著 Relevant Authoritative monograph 相关文献 Relevant literature	器械的预期用途相同吗? Is the expected function the same ?	■A1 预期用途相同 same □ A2 轻微偏差 minor difference □ A3 重大偏差 major difference	当暖贴温度为 45 度以下时，安全时间为 10000 秒，即大概为 166 分钟不被烫伤，从表 3、图 3、表 4 可以看出热敷超过 20 分钟的安全温度为 35℃-45℃之间，只要通过实验证明我公司产品的使用温度不超过 45℃，即可证明我公司的产品是安全的 according to figure 3, when the temperature is under	a、《建筑环境学》（第二版）朱颖心/主编 中国建筑工业出版社 *Architect environmentology(second edition) Zhu Yingxin/chief editor China Building Industry Press*

	temperature range given by relevant literature d、我公司产品的实际温度范围 Actual temperature range of our products				45℃, the safety time is 10000seconds, meaning that during about 166 minutes, one can't be scalded. From table 3, figure3 and table 4, it can be seen that the safe temperature is in 35℃ -45℃ within 20 minutes. as long as our product can be proved under 45℃ when be used, it can be said safe.	e、技术文档 CE-01-07 说明书对产品的使用方法、注意事项有描述，确保了客户如果正确按照说明书操作，the specification of the technique CE-01-07 illustrates the using method and notices of the product, ensuring the customers use the product in the right way.

5.4 产品有效性评价 Effectiveness evaluation	a、产品温度测试报告 b、产品临床经验温度数据 c、相关文献给出的安全温度范围 d、我公司产品的实际温度范围	相关科学实验 Relevant scientific experiment 相关权威专著 Relevant Authoritative 相关文献 Relevant literature	器械的预期用途相同吗？ Is the expected function the same ？	■A1 预期用途相同 same □ A2 轻微偏差 minor difference □ A3 重大偏差 major difference	热敷的有效温度为35℃-45℃之间，只要通过实验证明我公司产品的温度在这个温度范围内，即可证明我公司的产品是有效的，达到了取暖和热敷的预期用途 we know that the effective temperature of hot compress ranges from 35℃-45℃. As long as our product can be proved in this temperature range, it can said to safe and reach the expected hot compress and heating function	a、技术文档CE-01-07产品规格和参数“对各种规格产品的产品温度范围有描述 the product specifications and parameter of the technique CE-01-07 describe the temperature range of the products. b、产品温度测试报告 temperature test report of the product

6 结论 conclusion

6.1 我公司暖贴的所有风险都是可控的，受益大于风险，见本评估报告 5.1

All the risks of our warmer are controllable. The benefits overweight risks. Please refer to assessment report 5.1

6.2 我们所用到的临床评估材料或具有通用性，适用于所有热敷产品，或适用于等同器械或拟评价器械，所选用文献和材料是适宜的；见本评估报告 5.2

The literature and materials we use in clinical assessment are appropriate. They are suitable to hot compress products, equivalent products or draft assessment equipment.please refer to assessment report 5.2.

6.3 我公司暖贴是安全的：产品说说明书中有说明产品不能直接贴于皮肤上，必须贴于内衣上进行使用。

Our warmer pad is safe.we have reminded on the specification that the product can’t be put directly on skin and must be pasted on underwear.

6.4 我公司产品是有效的：热敷的有效温度为 35℃-45℃之间，而我公司产品加毛巾或贴于衣服上使用，完全可以保证在这个温度范围内，所以我公司产品是有效的。

Our product is effective: we know that the effective temperature of hot compress ranges from 35℃-45℃. Wrapped up with towel or pasted on underwear, the temperature can be ensured in the temperature range.

7 附件 enclosure

临床文献资料 clinical literature

产品温度测试报告 temperature test report of products

生产环境控制Production environment control

产品加工厂的生产环境控制，是通过以下文件进行控制The environmental control of products manufacturing plant, is controlled by the following documents：

文件名称File Name	文件编号File Number	版本 Version	生效日期 Effective Date
基础设施和工作环境控制程序 Basis Equipment and Working Environmental Control Procedure	HENGDA/QP-6.3-01	A/0	2011.10.25
作业环境状态点检表 Operation Environmental Status Checklist	HENGDA/QSR-05-11	A/0	2011.10.25

生产环境控制文件详见附件Production environmental control files in Annex。

1、Please see attachment Vigilance system Related control procedure：

《警戒系统控制程序》HENGDA/QP-9.0-02 Alert system control procedure

《过程和产品的监视和测量程序》HENGDA/QP-8.2.3-01Product monitoring and measurement control procedure

《生产和服务控制程序》HENGDA/QP-7.5.1-01 Production and service control procedure

《不合格品控制程序》HENGDA/QP-8.3-01 Control of nonconforming product procedure

《顾客满意度控制程序》HENGDA/QP-7.2-01 Customer Satisfaction control procedure

《纠正或预防措施管理程序》HENGDA/QP-8.5.2-01 Corrective and preventive actions management procedure

《发布忠告性通告管理程序》HENGDA/QP-8.5.1-02 Advisory notices management procedure

2、法定机构名单

COUNTIRIES/ NMES	COMPANIES	ADDRESSES	PHONE	FAX
AUSTRIS Dr.Ecker,Dr.Neumuller	Federal Ministry of LEMour,Health And Social Affairs	Stubenring,1 A 1010 Vienna	43/1/711.72.42.06 43/1/711.72.47.60	43/1/715.73.12
BELGIUM Mme Mouyat	The ministry of Health, Pharmaceutical Inspectorate, Medical Device Vigilance	Vesalius Building-Rijksadministratief Centrum B-1010 Brussels	32/2/210.63.58	32/2/210.48.80
Bulgaria	Bulgarian Drug Agency	Yanko Zakazov Blvd, 26 BG - 1504 Sofia Bulgaria	359 2 944 69 99	359 2 943 44 87
Cyprus	Cyprus Medical Devices Competent Authority	Prodromou 1 & Chilonos 17 Corner1449 Nicosia Cyprus	+357 22 605 572	+357 22 468 467
Czech Republic	Ministry of Health Competent Authority	Palackeho nEMesti 4, 128 01 Prague 2 Czech Republic	+420 224 972 738 +420 224 972 363	+420 224 916 002

DENMARK M. Hans-kristain Andersen	The National Board of Health Medicines Division (Emai:hka@dkma.dk)	Fredeerikssundsej 378 DK-2700 Bronshoj	45/44/889.111 45/44/889.265 (direct line)	45/44/839.195
Estonia	State Agency of Medicines Medical Devices Department	1 Nooruse st., 50411 Tartu Estonia	+37 27 37 41 40	+37 27 37 41 42
FINLAND M.H.Seitsonen	Medical Devices Centre Natinal Agency for Medical	ManneEMeimintie16 6-po BOX 55 FIN-00301 Helsinki	35/9/4733-4249	35/9/4733-4266
FRANCE Mr. J. Grisoni	Ministere de la sante ; Direction des Hopitaux(site materiovigilance:http/www.sante gouv. fr)	1 Place Fontenoy F-75350 paris 07SP	33/1/40/564436	33/1/40/564963
GERMANY Herm stoBlein	Bundesinstitut fur Arzneimittel und Medizin-produkte；Geschaftsstelle Medizinprodukte	Seestr.10-11D-13353 Berlin	49/30/45485384	49/30/786353065
GREECE Mr.E Papadeas	Ministry of Health,welfare and Social Services Biomedical Technology Department	17Aristoteleleous Street GR-101-87 Athes	30/1/5232821	30/1/5223246
Hungary	Authority for Medical Devices	Budapest 1245 Pf. 987.Hungary	+36 1 302 5060	+36 1 269 1255
IRELAND Mr B Ingoldsby	Department of Health	Hawkins House ; IRL-Dublin 2	353/1/6714711	353/1/6711947
ICELAND Mrs Haraldsdottir	Ministry of Health and Social Service	Lantavegur 116 Is-150 Reykjavik	35/45/609700	35/45/519165
ITALY Dottissa M. Marletta	Ministry of Health,Department 11	p.le Industria 20 ; 1-00144 ROMA	39/6/59942423	39/6/59942111
Latvia	Health Statistics and Medical Technologies State Agency Medical Devices Board for Latvia	12/22 Duntes street,Riga, Latvia, LV-1005	+371 7 501590	+371 7 501591
Liechenstein (EFTA)	EMt für Gesundheit	Äulestrasse 51 FL-9490 Vaduz Liechenstein	+423 23675 60	+423 23673 50
Lithuania	The State Health Care Accreditation Agency under the Ministry of Health of the Republic of Lithuania	Zalgirio str. 92 LT- 09303 Vilnius Lithuania	+370 5 261 51 77	+370 5 212 73 10
LUXEMBOURG Dr. Gerard Scharll	Division de la Medcine Curative	4 rue Auguste Lumiere L-1950 Luxembourg	352/4785633(4785 634)	352/480324
Malta	Malta Standards Authority	Second Floor, Evans Building, Merchants Street, Valletta VLT 03 Malta	+356 2124 2420	+356 2124 2406

NETHERLAND P.A.Loekemeijer	Staatstoezicht op de Volksgezondheid,Inspectie Voor de Gezondheidszorg	Po Box 5850NL-2280 HW Rijswijk	31/70/3406241	31/70/3407159
NORWAY Mrs Hagerup-Jenssen	National Board Health (Emil:ingeborg hagerup-jenssen@helsetilsynet .dep telemax.no)(website:http://www.helsetilsynet.no)	Po box 8128 Dep N-0032 Oslo	47/22/248953 47/22/248940	47/22/249017
Poland	Competent Authority Office for Registration of Medicinal Products, Medical Devices and Biocidal Products	ZEMkowska 41 03 – 736 Warsaw Poland	+48 22 4921170 +48 22 4921190	+48 22 4921199 +48 22 4921199
PORTUGAL a) Non-active Evices:Mrs.EMreu b) Active devices:Mr.Faria Gomes	INFARMED INSA	Parque Saude de Lisboa ; Av.Do Brasil,53p-1700 Lisboa Codex Av Padre Cruz P-1699 Lisboa Codex	351/1/7908500 351/1/7573557	351/1/7959116 351/1/7573671
Romania	Ministry of Health and FEMily	1-3, Cristian Popisteanu Street, Sector 1 010024,Bucharest Romania	+40 21 307 25 81	+40 21 307 25 85
Slovenia	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia	Ptujska ulica 21 SI-1000 Ljubljana Slovenia	+386 (0)8 2000 500	+386 (0)8 2000 510or +386 (0)8 2000 557
Slovakia	State Institute for Drug Control Medical Devices	SectionKvetna 11, 825 08 Bratislava 26 Slovak Republic	+421 2 50701215 +421 2 50701213	+421 2 55565151
SPAIN Carmen EMad Luna	Minidteril de sanidady Consumo Direccion General de Farmacia y products sanitarios	Paseo del prado 18/20 E-28071 Medrid	34/1/5964022	34/1/5964400
SWEDE Bo C. Hojdefors	National Board of Health and Welfare,Medical Devices	S-106 30 stockholm	46/8/7833499	46/8/7833294
SWITZERLAND Dr.Peter Frei	Office federal de la Sante publique	CH-3003 Bern	41/31/3229803	41/31/3227646
Turkey (Candidate)	Ministry of Health General Directorate of the Curative Services Biomedical Engineering Department Market Surveillance Section	Saglık Bakanlıgı Ek Binası, Atatürk Bulvarı No: 657. Kat Sıhhiye 06343 Ankara/TURKEY	+ 90 312 3240248	+90 312 3240378
UNITED KINGOOD Ron Dale	Adverse Incident Center,Department of Health,Room	Hnnibal House,Elephant and Castle ; UK-London SE16TQ	44/171/4928080	44/171/9728109
COMMISSION CONTACT Norbert Anselmann	DG III.D.2(Medical devices sector,SC153/133)	200,rue de la Loi,B-1049 Brussels	32/2/2959339 32/2/2959154 (Secretarial)	32/2/2967013