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宝康医疗

CE Technical Files

Product Name: Plaster of Paris Bandage, Orthopaedic Padding, Elastic Bandage

Prepared by: 章倪燕 Date: 2016年12月27日

Reviewed by: 赵荣珊 Date: 2016.12.27

Approved by: 周永 Date: 2016.12.27

Version B/0 Effective Date

安吉宝康医疗器械有限公司 330523036062

Applicant: Anji Baokang Medical Instrument Co., Ltd.
安吉宝康医疗器械有限公司
Address: Jingcun Village, Tianhuangping Town, Anji County, Zhejiang Province,China.
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1. Introduction of Manufacturer

1.1 Introduction of the Manufacturer

Anji Baokang Medical Instrument Co., Ltd., is located Anji County which is known as Chinese bamboo township. It is close to Shanghai Port, Ningbo Port and Hangzhou International Airport. The convenient transportation provides an easy access for our goods to be exported to the world markets.

Baokang Med is a professional manufacturer of various kinds of medical dressings: Plaster of Paris Bandage, Orthopaedic Padding, Elastic Bandage, Paraffin Gauze Dressings and Tubular Bandages. Our predominant product is Plaster of Paris (P.O.P) Bandage, made by advanced and scientific formulation with main technical criteria conforming to Britain's BP-88 standards. Our products with CE & ISO13485 approved are sold well in North America, Southeast Asia, the Middle East, East Europe, and West Europe.

1.2 Basic information of the Manufacturer

Applicant: Anji Baokang Medical Instrument Co., Ltd.

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Address: Jingcun Village, Tianhuangping Town, Anji County, Zhejiang Province, China.

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2. Introduction of Product

2.1 Classification

Plaster of Paris Bandage, Orthopaedic Padding, Elastic Bandage do not belong to the instruction of implantable medical device. According to the Rule 1, Annex IX (Rule 1: All non-invasive devices are in class I, unless one of the rules set out hereinafter applies.) of EU medical devices directive MDD（Medical Devices Directive, 93/42/EEC including Directive 2007/47/EC）, it shall be considered as Class I.

The certification will be conducted against Annex VII of 93/42/EEC

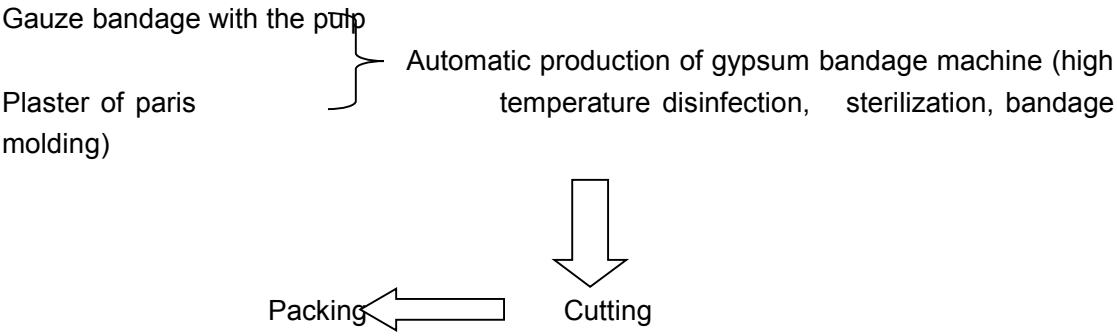
2.2 Product Information

Product Name	Size	Description	Picture
Plaster of Paris Bandage	Length:2.7M,3M,3.6M,4M, 4.6M Width:5CM,7.5CM,10CM, 15CM,20CM	Weight: 380GSM-420GSMSetting time,Individually wrppped by plastic bag,6-12 rolls per zipbag;Plaster of Paris Bandage adopts high-quality hemihydrates of calcium sulfate and high-quality cotton (40S, 29 x 19) gauze as its main materials. It is suitable for instant use and for treatment after surgery. Moreover, it is also can be used for model making, such as mask, mould, children toys etc.	
Orthopaedic Padding	Length:2.7M,3M,3.6M,4M, 4.6M Width:5CM,7.5CM,10CM, 15CM,20CM	Non-sterile,Material: polyester,cotton,viscose and the mixed materials;Weight: 75 GSM,1 roll/wrapper,6-12 rolls per zipbag,Orthopaedic Padding is a synthetic, protective orthopaedic, that blends excellent conformability and good cushioning, with a water-shedding ability that will keep the patients skin dry. The padding tears quickly and easily around awkward contours, minimising patient trauma and enhancing ease of application for the clinical user.	

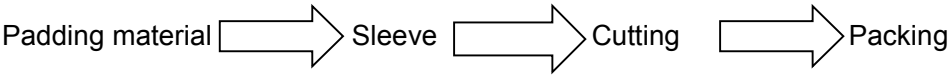
Product Name	Size	Description	Picture
Elastic Bandage	Length:4M,4.5M,5M Width:5CM,7.5CM,10CM, 15CM,20CM	Material:80%cotton and 20% spendex Major thermal injury on the extremities, soft tissue injury, joint swelling and pain have auxiliary treatment effect, also be applied to sprains and physical exercise in the protection and surgical dressings.Orthopedics, surgery, sports training protection, etc.	

3. Process chart

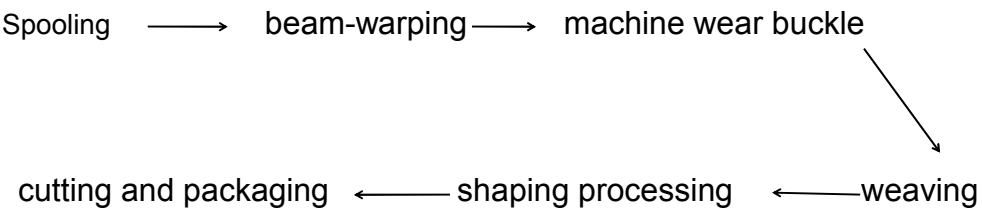
石膏绷带 Plaster of Paris Bandage



石膏衬垫 Orthopaedic Padding



弹性绷带 Elastic Bandage



4. Instruction for User

Instruction for Orthopaedic Padding

Orthopaedic padding is made of cotton woven cotton or viscose.

[Feature]

Soft, comfortable, high-temperature sterilization without deformation and easy to use

[Scope]

For orthopedic surgery to stop bleeding, infection with isolation of socks, plaster liner, when the tube hit the substrate, etc.

[How to Use]

1, Open the package, take the orthopaedic padding and remove the packaging

2, Uniformly wrapped around the affected area

[Warning]

1, Do not use excessive force or it will be broken

2, Stored in no more than 80% relative humidity, non-corrosive gas, a well-ventilated room

5-years shelf life

[Storage] Avoid high temperature & moisture.

Anji Baokang Medical Instrument Co., Ltd.
Jingcun Village, Tianhuangping Town, Anji County, Zhejiang Province, China.

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Instruction for Plaster of Paris Bandage

[Feature]

1. Bandages flooding, loss of little plaster;
2. The curing time control;
3. Hardness;
4. Fast drying time;
5. Adaptability, high temperature, cold, non-toxic, no stimulation, no allergy

[Scope]

For orthopedic fracture fixation, deformity correction, limb inflammation brake, osteomyelitis, bone tuberculosis, bone tumors and bone and joint arthroplasty, limb fixed and mold model making.

[How to Use]

1. Before use, wrap a layer of plaster tissue paper on the wound. Keep the hand clean and dry when open the package.
2. Impregnated:
   Put the bandage into the water with 45° angle until without any bubble, the time should not exceed 15s. (about 5s or so).
3. Extrusion:
   Take the bandage from the water carefully and then gently with both hands pressed against the edge from the center point of discharge excess water.
4. Shaping:
   Immediately wrap the bandage on the wound of patient and shape.
5. Smooth:
   Smooth the bandage continuously when use

[Warning]

1. Plaster should evenly adhere on supported gauze
2. In addition to the edge of a bandage formed by cutting a small amount of plaster debris, the cream should not be stripped unglued phenomenon.
3. The bandage should be smooth and without wrinkles.
4. Impregnated time should not exceed 15s.
5. The bandage should have good plasticity, there should be massive and coarse uneven shape.
6. Shaping time is not less than 2 minutes, no more than 15 minutes, 24 hours after curing should not be the phenomenon and also the soft layer, breakage.
7. It should be stored in dry and ventilated environment.
8. 5 years shelf life

[Storage] Avoid high temperature & moisture.

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Instruction for the Elastic Bandage

What is it? Elastic Bandage come in many different sizes and lengths. These bandages are sometime called elastic "roller" bandages, and are sold under brand names such as ACE?wrap. Elastic bandages come in rolls with metal clips, tape, or Velcro?to fasten them in place. You can buy them at a medical supply, grocery, or drug store. Your caregiver can help you choose the best bandage for you.

Why do I need it? An elastic bandage puts gentle pressure on the tissue around an injury. It also gives support to the injured area. You may need an elastic bandage for one or more of the following reasons:

- To help decrease pain and reduce swelling of an injured area.
- To hold wound bandages in place.
- To wrap around an arm or leg splint during healing.
- To improve blood flow to a limb like an arm or leg.
- To hold cold or hot packs in place on a body part, such as an arm.

How do I use an crepe bandage? Ask your caregiver to show you how to wrap the bandage. The following example may help you learn how to wrap an elastic bandage around an ankle. These directions may also be used to wrap the bandage around a hand, wrist, elbow, or knee.

- **Hold the bandage so that the roll is facing up.** This way, bandages containing Velcro?face the right way and stick to the bandage when you finish wrapping.

- Start the loose end of the bandage on the top of the foot.
- Hold the loose end of the bandage in place with one hand. With the other hand, wrap the bandage in a circle twice around the foot. Always wrap the bandage in the direction of outside (little toe side of foot) to inside (big toe side of foot).
- **Overlap the elastic bandage by one-half to one-third of its width each time you go around.**
- After the foot has been wrapped twice, move your hand to the heel.
- Wrap the bandage moving up toward the ankle. The bandage should be wrapped in a spiral way, like making a "figure 8". Leave the heel uncovered.
    - Cross the bandage over the foot, moving upward, and pass it behind the ankle.
    - Move the bandage down and cross it over the top of the foot.
    - Wrap the bandage under the foot to complete the "figure 8". Repeat this one more time.

- Pass the bandage around your calf and start wrapping it in upward circles toward your knee. Stop wrapping below the knee. You do not need to wrap the bandage down the calf again.
- Fasten the end to the rest of the bandage with tape, metal clips, or Velcro? Do not fasten metal clips on a bandage where there is a skin fold or crease, such as under the knee.

What can I do for safety and comfort?

- Do not to wrap the bandage too tight because it may cut off blood flow.
- To help with blood flow, take off the bandage at least two times a day if okay with your caregiver. Leave it off for a few minutes and wrap it again. Ask your caregiver if you should take off the elastic bandage at night.
- If you have numbness (loss of feeling) or tingling under the elastic bandage, remove the bandage. Gently rub the area. Rewrap the bandage when the area feels better.
- If the part of your body with the elastic bandage becomes cold or turns blue, remove the bandage.
- You may want to have an extra elastic bandage. Then you can wash one when it gets dirty and have the other elastic bandage to use.

Call your caregiver if:

- You have pain or cramping on the body part where the bandage is wrapped.
- You have tingling or numbness that does not go away after removing the bandage.
- The skin around the bandage looks blue, pale, and feels cold.
- You see redness that was not present when the bandage was first applied.

CARE AGREEMENT:

You have the right to help plan your care. To help with this plan, you must learn about your illness, injury, or surgery, and using an elastic bandage. You can then discuss your treatment options with your caregiver. You can work with them to decide what care will be used to treat you. You always have the right to refuse treatment.

Information is for End User's use only and may not be sold, redistributed or otherwise used for commercial purposes.

The above information is an educational aid only. It is not intended as medical advice for individual conditions or treatments. Talk to your doctor, nurse or pharmacist before following any medical regimen to see if it is safe and effective for you.

[Storage] Avoid high temperature & moisture.

Anji Baokang Medical Instrument Co., Ltd.
Jingcun Village, Tianhuangping Town, Anji County, Zhejiang Province, China.

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5. Applicable Standards

No.	File No.	Version	File Title
1	MDD 93/42/EEC including Directive 2007/47/EC	2007	Medical Device Directive
2	EN ISO 14971	2012	Medical Device -Application of Risk Management in Medical Device
3	EN ISO 15223-1	2012	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied General requirements.
4	EN 1041	2008	Terminology, Symbols and Information Related to Medical Devices –Information Provided by Manufacturers of Medical Devices
5	EN ISO 10993-1	2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
6	EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
7	EN ISO 10993-10	2013	Biological Evaluation of Medical Device –Part 10: Irritation and Sensitization Test

6. Label and Language

6.1 General

This Clause contains symbols that are already in use, and are deemed to be suitable without need for further explanation.

NOTE Symbols used with medical devices for use by other than healthcare professionals can require additional explanations.

6.2 Symbol for "DO NOT REUSE"

NOTE 1 Synonyms for "Do not reuse" are "single use", "Use only once"

6.3 Symbol for “BATCH CODE”

This symbol shall be accompanied by the manufacturer's batch code. The batch code shall be adjacent to the symbol

NOTE 1 The relative size of the symbol and the size of the batch code are not specified.

NOTE 2 Synonyms for "batch code" are "lot number", "batch number".

6.4 Symbol for "CONSULT INSTRUCTIONS FOR USE"

NOTE 1 Synonym for "Consult instructions for use" is "Consult operating instructions".

NOTE 2 This symbol corresponds to that given in ISO 7000-1641 and to symbol number 5.3 in ISO 15223-1:2007.

6.5 Symbol for "DATE OF MANUFACTURE"

This symbol shall be accompanied by a date to indicate the date of manufacture, expressed as given in ISO 8601, as four digits for the year, and where appropriate, two digits for the month and

two digits for the day. The date could be a year, year and month, or year, month, and day, as required by the relevant Directive. The date shall be located adjacent to the symbol (see A.4).

NOTE 1 The relative sizes of the symbol and the date are not specified.

6.6 Symbol for "CATALOGUE NUMBER"

The manufacturer's catalogue number shall be after or below the symbol adjacent to it (See A.5).

NOTE 1 The relative size of the symbol and the size of the catalogue number are not specified.

NOTE 2 Synonyms for "catalogue number" are "reference number", "re-order number".

6.7 Symbol for "CAUTION"

NOTE 1 This symbol is essentially a safety symbol and should be used to highlight the fact that there are specific warnings or precautions associated with the device, which are not otherwise found on the label. The symbol “Caution” is still sometimes used to have the meaning of “Attention, see instructions for use” (see 5.18).

6.8 Symbol for "MANUFACTURER"

This symbol shall be accompanied by the name and the address of the manufacturer (the person placing the device on the market), adjacent to the symbol (see A.6).

NOTE 1 The relative size of the symbol and the size of the name and address are not specified.

NOTE 2 The full definition of ‘manufacturer’ is given in Council Directives 90/385/EEC, 93/42/EEC including Directive 2007/47/EC and 98/79/EC.

NOTE 3 The date of manufacture as well as the name and address of the manufacturer can be combined in one symbol (see A.7).

6.9 Symbol for "AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY"

This symbol shall be accompanied by the name and the address of the authorised representative in the European Community, adjacent to the symbol (see A.8).

NOTE The relative size of the symbol and the size of the name and address are not specified.

b) Diameter of the pattern shall not be less than 5mm.

c) CE marking shall be distinct, visible, durable and in clear writing.

6.10 After passing CE certification, mark of CE needs to be printed on labels;

a) Pattern CE

b) Diameter of the pattern shall not be less than 5mm.

c) CE marking shall be distinct, visible durable and in clear writing.

A.2 Example of use of symbol for "BATCH CODE"

LOT ABC123

A.4 Examples of use of symbol for "DATE OF MANUFACTURE"

2004-06

2005 

A.5 Examples of use of symbol for "CATALOGUE NUMBER"

REF ABC123

A.6Example of use of symbol for "MANUFACTURER"

公司地址

A.7Example of use of symbol for “MANUFACTURER” combined with “DATE OFMANUFACTURE”

公司地址
2005-06

A.8Example of use of symbol for " AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY"

EC REP 公司地址

CE Technical Files

Language / Country	Denish	Dutch	English	Finnish	French	German	Greek	Icelandic	Italian	Norwegi	Portugue	Spanish	Swedish	Czech	Estonian	Russian	Hungaria	Latvian	Lithuania	Polish	Slovak	Slovesn
Austria						★																
Belgium		★			★	★																
Denmark	★																					
Finland				★									★									
France					★																	
Germany						★																
Greek							★															
Holland		★																				
Iceland								★														
Ireland			★																			
Italy									★													
Luxembourg					★	★																
Norway										★												
Portugal											★											
Spain												★										
Sweden													★									
Switzerland					★	★																
UK			★																			
Cyprus							★															
Czech														★								
Estonia			★												★	★						
Latvia			★													★		★				
Lithuania																			★			
Malta			★																			
Poland																				★		
Slovakia																					★	
Slovenia																						★
Hungary																	★					

Product Name

SIZE/MODEL: XXXXX

YYYY-MM-DD

LOT YYYYMMDD

YYYYMMDD

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EC REP

Anji Baokang Medical Instrument Co., Ltd.
Jingcun Village, Tianhuangping Town, Anji County, Zhejiang Province, China.

The above label is applied to Plaster of Paris Bandage, Orthopaedic Padding, Elastic Bandage

7. EC Declaration of Conformity

See Declaration of Conformity

(File No: CE-TCF-001)

8. Essential Requirement Checklist

See Checklist of Essential Requirements

(File No: CE-TCF-002)

9. Risk Analysis Report

See Risk Analysis Report

(File No: CE-TCF-003)

10. Test Report

See Test Report

(File No: CE-TCF-004)

11. The Evaluation from the user in the Market

See The Evaluation from the user in the Market

(File No: CE-TCF-005)

12. Attachment List and Attachments

No.	File No.	File Title
1	CE-TCF-001	EC Declaration of Conformity
2	CE-TCF-002	Essential Requirements Report
3	CE-TCF-003	Risk Analysis Report
4	CE-TCF-004	Test Report
5	CE-TCF-005	The Evaluation from the user in the Market

File No: CE-TCF-001

EC Declaration of Conformity

Regarding Medical Device Directive(93/42/EEC)

including Directive 2007/47/EC

Applicant

Name: Anji Baokang Medical Instrument Co., Ltd.

Address: Jingcun Village, Tianhuangping Town, Anji County, Zhejiang Province,China.

Product

Name	Type
Plaster of Paris Bandage	Length:2.7M,3M,3.6M,4M,4.6M Width:5CM,7.5CM,10CM,15CM,20CM
Orthopaedic Padding	Length:2.7M,3M,3.6M,4M,4.6M Width:5CM,7.5CM,10CM,15CM,20CM
Elastic Bandage	Length:4M,4.5M,5M Width:5CM,7.5CM,10CM,15CM,20CM

Classification: I

Rule: According to Rule 1

We confirm our product can meet the requirement of Medical Device Directive and the following harmonized standards.

EN ISO 14971:2012
EN ISO 15223-1:2012
EN 1041:2008
EN ISO 10993-1:2009/AC:2010
EN ISO 10993-5:2009
EN ISO 10993-10:2013

Signature:

Date: 2016.12.2

Checklist of Essential Requirement

The requirement of Medical Device Directive 93/42/EEC amended by 2007/47/EC	Applicable	Standard	Evidence of Conformity
I. GENERAL REQUIREMENTS 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. 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 —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).	A	EN ISO 15223-1 EN ISO 14971 EN ISO 10993-1 EN ISO 10993-5 EN ISO 10993-10	Label Risk analysis report Test report
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, – inform users of the residual risks due to any shortcomings of the protection measures adopted.	A	EN ISO 14971	Risk analysis report
3.The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they	A	EN ISO 10993-1 EN ISO 10993-5 EN ISO 10993-10	Test report

are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer.		EN 14683 EN ISO 15223-1	Label
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 conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use.	A	EN ISO 15223-1	Label
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.	A	EN ISO 15223-1 EN ISO 14971	Label Risk analysis report
6. Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended. 6a. Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X.	A	EN ISO 14971	Risk analysis report
7.1. The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section I 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 modeling research whose validity has been demonstrated beforehand.	A	EN ISO 10993-1 EN ISO 10993-5 EN ISO 10993-10	Test report
7.2 The devices must be designed, manufactured and packed in such a way as to minimize 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	A	EN ISO 14971	Risk analysis report

must be paid to the tissues exposed and to the duration and frequency of exposure.			
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 these products and that their performance is maintained in accordance with the intended use.	A	EN ISO 15223-1 EN ISO 14971 EN ISO 10993-1 EN ISO 10993-5 EN ISO 10993-10	Label Risk Analysis Report Test Report
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. 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 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. Where a device incorporates, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as	NA		

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 its 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. 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. When the relevant medicines competent authority (i.e. the one involved in the initial consultation) has obtained information on the ancillary 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.			
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	NA		

are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labeling of dangerous substances. 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, these devices must be labeled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates. 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.			
7.6 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 into the device taking into account the device and the nature of the environment in which it is intended to be used.	NA		
8.1 The devices and manufacturing processes must be designed in such as 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, minimize contamination of the device by the patient or vice versa during use.	A	EN ISO 14971	Risk analysis report

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. Notified bodies shall retain information on the geographical origin of the animals. 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 transferable agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.	NA		
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 that 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.	NA		
8.4 Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.	NA		
8.5 Devices intended to be sterilized must be manufactured in appropriately controlled (e.g. environmental) conditions.	NA		
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 sterilized prior to use, minimize the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer.	NA		
8.7 The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition.	A	EN 1041 EN ISO 15223-1	Instruction of use Label
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 performances of the devices. Any restrictions on use must be indicated on the label or in the	NA		

instructions for use.			
9.2 Devices must be designed and manufactured in such a way as to remove or minimize as far as is possible: – the risk of injury, in connection with their physical features, including the volume/pressure ration, dimensional and where appropriate ergonomic features, – risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration, – the risks of reciprocal interference with other devices normally used in the investigations of for the treatment given, – Risks arising when maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.	NA		
9.3. Devices must be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and single fault condition. Particular attention must be paid to devices whose intended use includes exposure to flammable substances or to substances which could cause combustion	NA		
10 Devices with a measuring function 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. 10.2 The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device. 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.	NA		

11.1 General 11.1.1 Devices shall be designed and manufactured in such a way 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.	NA		
11.2 Intended radiation 11.2.1 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. 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.	NA		
11.3 Unintended radiation 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 reduced as far as possible.	NA		
11.4 Instructions 11.4.1 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 of eliminating the risks inherent in installation.	NA		
11.5 Ionizing radiation 11.5.1 Devices intended to emit ionizing radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking into account the intended use.	NA		
11.5.2 Devices emitting ionizing radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve	NA		

appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.			
11.5.3 Devices emitting ionizing 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 radiation.	NA		
12.1. Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to the 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. 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.	NA		
12.2 Devices where the safety of the patients depends on an internal power supply must be equipped with a means of determining the state of the power supply.	NA		
12.3 Devices where the safety of the patients depends on an external power supply must include an alarm system to signal any power failure.	NA		
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.	NA		
12.5 Devices must be designed and manufactured in such a way as to minimize the risks of creating electromagnetic fields, which could impair the operation of other devices or equipment in the usual environment.	NA		
12.6 Protection against electrical risks 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	NA		

in single fault condition, provided the devices are installed correctly.			
12.7 Protection against mechanical and thermal risks 12.7.1 Devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risk connected with, for example, resistance, stability and moving parts.	NA		
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, particularly at source, unless the vibrations are part of the specified performance.	NA		
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.	NA		
12.7.4 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 minimize all possible risks.	NA		
12.7.5 Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.	NA		
12.8 Protection against the risks posed to the patient by energy supplies or substances 12.8.1 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.	NA		
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.	NA		

Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.			
12.9 The function of the controls and indicators must be clearly specified on the devices. 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.	NA		
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. This information comprises the details on the label and the data in the instructions for use. 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. Instructions for use must be included in the packaging for every device. By way of exception, no such instructions for use are needed for devices in Class I or IIa if they can be used safely without any such instructions.	A	EN 1041 EN ISO 15223-1	Instruction of use Label
13.2 Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device.	A	EN 1041	Instruction of use
13.3 The label must bear the following particulars: (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 authorized representative	A	EN ISO 15223-1 EN 1041	Label Instruction of use

where the manufacturer does not have a registered place of business in the Community;			
b) the details strictly necessary for the user to identify the device and the contents of the packaging;	A	EN 1041 ENI SO 15223-1	Instruction of use, Label
c）where appropriate, the word 'STERILE';	NA		
d）where appropriate, the batch code, preceded by the work 'LOT', or the serial number;	A	EN 1041 EN ISO 15223-1	Instruction of use, Label
e）where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and the month;	A	EN 1041 EN ISO 15223-1	Instruction of use, Label
(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;	A	EN 1041 EN ISO 15223-1	Instruction of use, Label
G）if the device is custom-made, the words 'custom-made device';	NA		
H）if the device is intended for clinical investigations, the words 'exclusively for clinical investigations';	NA		
I）any special storage and/or handling conditions;	A	EN 1041 EN ISO 15223-1	Instruction of use, Label
J）any special operating instructions;	NA		
K）any warnings and/or precautions to take;	A	EN ISO 15223-1	Label
L）year of manufacture for active devices other than those covered by (e). This indication may be included in the batch or serial number;	A	EN 1041 EN ISO 15223-1	Instruction of use, Label
M）where applicable, method of sterilization.	NA		
N） in the case of a device within the meaning of Article 1 (4a), an indication that the device contains a human blood derivative.	NA		
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.	A	EN 1041	Instruction of use
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	NA		

risk posed by the devices and detachable components.			
13.6 Where appropriate, the instructions for use must contain the following particulars: a) the details referred to in Section 13.3, with the exception of (d) and (e);	A	EN 1041	Instruction of use
b) the performances referred to in Section 3 and any undesirable side-effects;	A	EN 1041	Instruction of use
c) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for it intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination;	NA		
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;	NA		
e) where appropriate, information to avoid certain risks in connection with implantation of the device;	NA		
f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment	NA		
g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization;	NA		
(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 the device to be resterilized, and any restriction on the number of reuses.	NA		
i) Details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.);	NA		
j) in the case of devices emitting radiation for medical purposes, details of the nature, type intensity and distribution of this radiation. The instructions for use must also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken.	NA		

These details should cover in particular:			
k) precautions to be taken in the event of changes in the performance of the device;	A	EN 1041	Instruction of use
l) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;	NA		
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;	NA		
n) precautions to be taken against any special, unusual risks related to the disposal of the device;	NA		
(o) medicinal substances, or human blood derivatives incorporated into the device as an integral part in accordance with Section 7.4;	NA		
p) Degree of accuracy claimed for devices with a measuring function.	NA		
(q) Date of issue or the latest revision of the instructions for use.	A	EN 1041	Instruction of use

Risk Analysis Report

Identification of qualitative and quantitative characteristics (acc.to EN ISO14971:2012, cl. 4.2)

Questions	Answer
C.2.1 What is the intended use and how is the medical device to be used?	For orthopedic fracture fixation, deformity correction, limb inflammation brake, osteomyelitis, bone tuberculosis, bone tumors and bone and joint arthroplasty, limb fixed and mold model making
C.2.2 Is the medical device intended to be implanted?	No
C.2.3 Is the medical device intended to be in contact with the patient or other persons?	Yes, not contact with the destruction skin, just for external patient support
C.2.4 What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?	Polyester
C.2.5 Is energy delivered to or extracted from the patient?	NO.
C.2.6 Are substances delivered to or extracted from the patient?	NO.
C.2.7 Are biological materials processed by the medical device for subsequent re-use, transfusion or transplantation?	NO.
C.2.8 Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?	NO.
C.2.9 Is the medical device intended to be routinely cleaned and disinfected by the user?	NO.
C.2.10 Is the medical device intended to modify the patient environment?	NO.
C.2.11 Are measurements taken?	NO.
C.2.12 Is the medical device interpretative?	NO.
C.2.13 Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?	NO.
C.2.14 Are there unwanted outputs of energy or substances?	NO.
C.2.15 Is the medical device susceptible to environmental influences?	Avoid high temperature & moisture.
C.2.16 Does the medical device influence the environment?	NO.
C.2.17 Are there essential consumables or accessories associated with the medical device?	NO.
C.2.18 Is maintenance or calibration necessary?	NO.
C.2.19 Does the medical device contain software?	NO.
C.2.20 Does the medical device have a restricted shelf-life?	Five years
C.2.21 Are there any delayed or long-term use effects?	NO.

C.2.22 To what mechanical forces will the medical device be subjected?	NO.
C.2.23 What determines the lifetime of the medical device?	Product material
C.2.24 Is the medical device intended for single use?	Single use.
C.2.25 Is safe decommissioning or disposal of the medical device necessary?	NO.
C.2.26 Does installation or use of the medical device require special training or special skills?	NO.
C.2.27 How will information for safe use be provided?	Manual.
C.2.28 Will new manufacturing processes need to be established or introduced?	NO.
C.2.29 Is successful application of the medical device critically dependent on human factors such as the user interface? C.2.29.1 Can the user interface design features contribute to use error?	NO.
C.2.29.2 Is the medical device used in an environment where distractions can cause use error?	NO.
C.2.29.3 Does the medical device have connecting parts or accessories?	NO.
C.2.29.4 Does the medical device have a control interface?	NO.
C.2.29.5 Does the medical device display information?	NO.
C.2.29.6 Is the medical device controlled by a menu?	NO.
C.2.29.7 Will the medical device be used by persons with special needs?	NO.
C.2.29.8 Can the user interface be used to initiate user actions?	NO.
C.2.30 Does the medical device use an alarm system?	NO.
C.2.31 In what way(s) might the medical device be deliberately misused?	NO.
C.2.32 Does the medical device hold data critical to patient care?	NO.
C.2.33 Is the medical device intended to be mobile or portable?	Portable
C.2.34 Does the use of the medical device depend on essential performance?	NO.

No	Hazard	Identify hazards	Risk Evaluation				Risk Reduction Measure	Evidence	NH	ALOR
	General		S	O	D	RL				
D2.	**Energy Hazards**									
1	Electricity	N/A								
2	Heat	N/A								
3	Mechanical force	N/A								
4	Ionizing radiation	N/A								
5	Non Ionizing radiation	N/A								
6	Electromagnetic fields									
7	Moving parts	N/A								
8	Suspended masses	N/A								
9	Patient support device failure	N/A								
10	Pressure(vessel rupture)	N/A								
11	Acoustic pressure	N/A								
12	Vibration	N/A								
13	Magnetic fields(e.g. MRI)	N/A								
D3.	**Biological hazards**									
1	Bio-contamination	The product may be contaminated if the package is damaged.	2	3	1	6	Single use and package control	Instruction		Acc
2	Bio-incompatibility	The product may cause the user uncomfortable if the material is not OK	2	4	1	8	Choose raw materials of fabrics with qualified biological properties	See test report		Acc
3	Incorrect formulation(chemical composition)	The product may cause the user uncomfortable if the material is not OK	2	3	1	6	Choose safe chemical raw material in recognize to ensure that the ingredients are accurate.	See test report		Acc

No	Hazard	Identify hazards	Risk Evaluation				Risk Reduction Measure	Evidence	NH	ALOR
	General		S	O	D	RL				
4	Toxicity	The product may cause the user uncomfortable if the material is not OK	2	4	1	8	Choose raw materials of fabrics with cyto toxicity meeting the requirements	See test report		Acc
5	Allergenicity	N/A								
6	Mutagenicity	N/A								
7	Oncogenicity	N/A								
8	Teratogenicity	N/A								
9	Carcinogenicity	N/A								
10	Re-and/or cross-infection	The product is single use product and could not be re used.	2	3	2	12	Ensure that the products are for single use shall be shown on the instruction of use and labels.	Instruction of use and Labels		Acc
11	Pyrogenicity	The product may cause the user uncomfortable if the material is not OK	2	3	1	6	Ensure that microb content in the production environment meets the requirements.	Products operating instructions		Acc
12	Inability to maintain hygienic safety	The product may cause the user uncomfortable if the material is not OK	2	3	2	12	Ensure that microb content in the production environment meets the requirements.	Products operating instructions		Acc
13	Degradation	N/A								

No	Hazard General	Identify hazards	Risk Evaluation S	O	D	RL	Risk Reduction Measure	Evidence	NH	ALOR
D4.	**Environmental hazards and contributory factors**									
1.	Electromagnetic fields	N/A								
2.	Inadequate supply of power or coolant	N/A								
3.	Susceptibility to electromagnetic interference	N/A								
4.	Emissions of electromagnetic interference	N/A								
5.	Inadequate supply of power or coolant	N/A								
6.	Inadequate supply of coolant	N/A								
7.	Storage or operation outside prescribed environmental conditions	N/A								
8.	Incompatibility with other devices	N/A								
9.	Accidental mechanical damage	N/A								
10.	Contamination due to waste products and /or device disposal	N/A								

No	Hazard	Identify hazards	Risk Evaluation				Risk Reduction Measure	Evidence	NH	ALOR
	General		S	O	D	RL				
D5. Hazards resulting from incorrect output of energy and substances										
1.	Electricity	NA								
2.	Radiation	NA								
3.	Volume	NA								
4.	Pressure	NA								
5.	supply of medical gases	NA								
6.	supply of anaesthetic agents	NA								
D6. Hazards related to the use of the device and contributory factors										
1	Inadequate labeling	The inadequate labeling may cause misuse	2	2	1	4	Strengthen amending the label for warning	Refer to label		Acc
2	Inadequate operating instructions	The inadequate operating instructions may cause misuse	2	2	1	4	Strengthen amending the operating instructions	See instruction of use		Acc
2.1	Inadequate specification of accessories	NA								
2.2	Inadequate specification of pre-use checks	The device may be damaged	2	2	1	4	To strengthen pre-use checks	See instruction of use		Acc
2.3	Over-complicated operating instructions	NA								
2.4	Inadequate specification of service and maintenance	NA								
3	Use by unskilled/untrained personnel	The device may be damaged	2	3	1	6	To strengthen training	See instruction of use		Acc

No	Hazard	Identify hazards	Risk Evaluation				Risk Reduction Measure	Evidence	NH	ALOR
	General		S	O	D	RL				
4	Reasonably foreseeable misuse	NA								
5	Insufficient warning of side effects	The device has no side effects								
6	Inadequate warning of hazards likely with re-use of single use devices	NA								
7	Incorrect measurement and other metrological aspects	NA								
8	Incompatibility with consumables/accessories/other devices	NA								
9	Sharp side	NA								
D7. Complicated operation										
1	Mistakes and judgement errors	NA								
2	Lapses and cognitive recall errors	NA								
3	Slips and blunders (mental or physical)	NA								

No	Hazard	Identify hazards	Risk Evaluation				Risk Reduction Measure	Evidence	NH	ALOR
	General		S	O	D	RL				
4	Violation or abbreviation of instructions, procedures, etc.,	NA								
5	Complex or confusing control system	NA								
6	Ambiguous or unclear device state	NA								
7	0Ambiguous or unclear presentation of settings, measurements or other information	NA								
8	Mispresentation of results	NA								
9	Insufficient visibility, audibility or tactility	NA								
10	Poor mapping of controls to action, or of displayed information to actual state	NA								
11	Controversial modes or mappings as compared to existing equipment	NA								

No	Hazard	Identify hazards	Risk Evaluation				Risk Reduction Measure	Evidence	NH	ALOR
	General		S	O	D	RL				
D8. Hazards arising from functional failure, maintenance and ageing										
1	Erroneous data transfer	NA								
2	Lack of , or inadequate specification for maintenance including inadequate specification of post maintenance functional checks	The device may not work well if lack of inadequate post maintenance or functional checks	2	1	3	6	Strengthen post maintenance and functional checks	See instruction of use		ACC
3	Inadequate maintenance	The lifetime of the device may be reduced	1	2	2	4	Strengthen management	See instruction of use		ACC
4	Lack of adequate determination of end of device life	NA								
5	Loss of mechanical integrity	NA								
6	Inadequate packaging(contamination and /or deterioration of the device)	The lifetime of the device may be reduced	3	2	1	6				Acc
7	Re-use and / or Improper re-use	NA								
8	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.	NA								

B2. Additional hazards to in vitro diagnostic medical devices								
1	Batch inhomogeneity, batch-to-batch inconsistency	NA						
2	Common interfering factors	NA						
3	Carry-over effects	NA						
4	Specimen identification errors	NA						
5	Stability problems (in storage, in shipping, in use, after first opening of the container)	NA						
6	Problems related to taking, preparation and stability of speciments	NA						
7	Inadequate specification of prerequisites	NA						
8	Inadequate test characteristics	NA						

Abbreviations used

RE	Risk Evaluation
S	Severity (9 –very severe, 0 –not severe)
O	Occurrence (9 –often, 0 –never)
D	Detection (9 –impossible to detect before risk occurs, 0 –will be certainly detected before risk occurs)
RL	Risk Level = Severity × Occurrence × Detection 1-9: Neglectable risk, no further actions; 9-24: Moderate: minimal risk, preventive action recommended; 25-48: Moderate risk, preventive action required; >48: Risk is usually not acceptable
RRM	Risk Reduction Measure
NH	New hazard generated (no/ yes - if yes, then number of new hazard indicated)
ALOR	Acceptable Level of Risk

Conclusion:

According to the analysis of the risk, all the risk has been identified and the risks which are none accepted have been controlled by measure taken by the manufacturer. In one word, the risk has been managed accordingly.

弹 性 绷 带 质 量 检 验 单
CERTIFICATE OF ANALYSIS OF MEDICARE CREPE BANDAGE

Contract No.: 20160511

规　　格 (SPECIFICATION)	卷　　数 (QUANTITY)	箱　数 (CARTONS)
10cm×4.5m	36000rolls	100boxes

序号 NO.	检验项目 Testing Items	标　准　要　求 Standard	检验结果 results
1	外观要求 Appearance	1．织物应清洁，不允许有并丝。 The bandage must be clean.	Pass
		2．不允许有缺经，缺纬，跳针。 No allawance without weftand warp.	Pass
		3．无破洞和杂物，色泽均匀，无拼接。 No hold the colour should be average, without joints.	Pass
2	平方克重 Mass per suuare	4．绷带每平方米重量不少于 75±2 克。 Not less than 75g±2/㎡ for bandage.	75g/㎡
3	基本尺寸 Basic Dimension	5. 绷带长度偏为±10CM，宽度偏差±3MM。 More or less 10cm for bandage length, more of less 3mm for bandage width.	长 101mm, 宽 450cm
4	含量 Content	6．氨纶 20% Spandex 20%	20%
		7．棉纱 80% Cotton 80%	80%
5	伸展率 Strentched	8．大于等于 180% More or equal 180%	182%
质检科意见 Comments From Inspection Section		经检验，此产品符合相关行业和企业标准，准予出厂。 The above results are in compliance with standard.	
备注 （Remarks）			

检验 Inspector： 徐莎　　核校 Corrector： 郎乐乐

批准 Ratifier： 杨婷婷　　日期 Date： 2016 年 5 月 23 号

安吉宝康医疗器械有限公司
ANJI BAOKANG MEDICAL INSTRUMENT CO.,LTD
石膏绷带质量检验报告单
QUALITY TEST REPORT OF PLASTER OF PARIS BANDAGE

合同单位Contractor：上海翰尔升进出口有限公司					
品名Name of Products：Plaster of Paris Bandage			批号 Lot No.:161003		
规格 Size	数量/卷	箱数	规格 Size	数量/卷	箱数
10CMx2.7M	1560	13			
15CMx2.7M	5400	45			
20CMx2.7M	2700	45			
合计 Total	9660rolls/103cartons				

检验项目 EXAMINATIONITEM	标准要求 Standard Requirements	检验结果 Test Results	结论 Conclusion
纱布 GAUZE	克重量 WEIGHT PER UNIT AREA 24g/m^2	24g/㎡	PASS
	经纬度 WARP AND WEFT 29x18 in	29x18 in	PASS
外观 APPEARANCE	纱布细度 YARN 40 S	40'S	PASS
绷带克重量 GRAMMAGE	≥420g/㎡	423g/㎡	PASS
浸水时间 DIPPING TIME	5-15s	8s	PASS
湿落粉 FALLING	Within 3 % when immersion	2%	PASS
初凝时间	90-120s	100s	PASS
固化时间 SOLIDIFIED TIME	根据合同 3-5 Minutes	3:31minutes	PASS
可塑性 PLASTICITY	可塑性好 Good Plasticity	Good Plasticity	PASS
升温时间 HEAT TIME	265-420 S	270s	PASS
半水石膏含量 $Caso_4$ 1/2H_2O	≥88%	89%	PASS
最大发热量 EXOTHERMIC	39-42℃ When 15 minutes	40℃	PASS
固化强度 STRENGTH AFTER SOLIDIFIED	3.2 -4.8 N min When 15 Trillion platinum	4.2N	PASS
干燥时间 DRYING TIME	360-720 Minutes	365minutes	PASS
单卷袋包装 INDIVIDUALLY PACKING	密封收缩膜 waterproof and airtight pouch	waterproof and airtight	PASS
规格尺寸 MEASURE	宽度 Width 100,150,200±2mm	100mm,150mm, 200mm	PASS
	长度 Length270±5cm	270cm	PASS

质检部意见 VIEWS OF QUALITY INSPI	备注 REMARK
产品符合英国BP标准 Complying with British BP standard	PASS

检验Tested by: Zhang Renan　　审核Checked by：Yang Tingting　　批准Approved by： Lang Lele　　日期D

安 吉 宝 康 医 疗 器 械 有 限 公 司

ANJI BAOKANG MEDICAL INSTRUMENT CO.,LTD

质 量 检 验 结 论 报 告

THE QUALITY TEST REPORTS

Contract NO:20160423 **Test Date:2016-5-15**

品名(Name of goods)	规格(size)	卷数(QTY)
ORTHOPAEDIC PADDING	10CM×2.75CM 15CM×2.75CM	10800rolls

序号 NO.	检验项目 ITEM	标 准 要 求 Standard requirement	检验结果 Test results	结论 Conclusion
1	材质 material	100%化纤。 100% polyester.	PASS	PASS
2	定量 weight	每平方米为 70±3 克。 Grammage:70±3 g/㎡	75g/㎡	PASS
3	厚度 width	直径为 65±2MM。 More or less 65mm±2	5.6mm	PASS
4	颜色 colour	漂白 Bleaching White.	PASS	PASS
5	基本尺寸 Basic Dimension	宽度偏差为±2MM。 More or less 2mm for bandage width.	15,20cm	PASS
		绷带长度偏差为±10CM。 More or less 10cm for bandage length	2.7m	PASS
6	断裂强度 Strengh	向为 20N。 warp 20N	PASS	PASS
		纬向为 35N。 weft 35N	PASS	PASS
7	PH 值值 PH VALUE	中性 NEUTREAL	PASS	PASS
质检科意见 (Commernts From Inspection Section)		经检验，此产品符合相关行业和企业标准，准予出厂。 The above results are in compliance with standard.		
备注 (Remarks)				

检验 Tested by：郎乐乐 批准 Approved by： 杨婷婷

Certificate of Registration

nqa global assurance

This is to certify that the Quality Management System of

Anji Baokang Medical Instrument Co., Ltd.

Organization Code : 57396018-0

Operation Address : Jingcun Village, Tianhuagping Town, Anji County, Huzhou City, Zhejiang Province, China

Registered Address : Jingcun Village, Tianhuagping Town, Anji County, Huzhou City, Zhejiang Province, China

applicable to

Production and sales of Plaster of Paris Bandage and Orthopaedic Padding; production and sales of Elastic Bandage and Medical Bandages (for export only)

has been assessed and registered by NQA against the provisions of

ISO 13485: 2003

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)

SNQA's website : www.snqa.com.cn

Certification Director

Certificate Number **35566**

Date: 06 December 2011

Reissue Date: 02 December 2014

Valid Until: 02 December 2017

EAC Code: 04

UKAS MANAGEMENT SYSTEMS 015

The use of the UKAS Accreditation Mark indicates accreditation in respect of those activities covered by the accreditation certificate number 015 held by NQA.

NQA is a trading division of Ascertiva Group Ltd, Registration No.02513162. Registered Office: Warwick House, Houghton Hall Park,Houghton Regis, Dunstable, Bedfordshire, LU5 5ZX.

This certificate is the property of NQA and must be returned on request.

The evaluation from the user in the market

1. The product has been put into the market for several years and the customer satisfactory was investigated each year. And at the same time, the client could report the accident and the problems of the product to the department of the government.

2. Form the result of the investigation and the feedback from the customer, the product is safe to be used.

关于确定欧洲代表的声明

本公司目前无产品销售到欧洲地区，也无确定欧洲代表，今后在产品出口欧洲之前确定好欧洲商及欧洲代表地址等，然后通知认证机构。

销售部张涛　　2016.12.2

职位　　签名　　日期

Concerning European Representative Established within European Community

We have not sold products in Europe and not appointed European Representative established within European Community. We will nominate Distributor and Authorized Representative Established within European Community and inform Certification Body before our products were exported to Europe.

Sales Manager.　　July-zeng　　2016.12.2

Post　　signature　　date