Product Data Sheet

Product: Retrieval Pouch

Type Reference: Laparoscopic/Surgical Instrument and Accessories

Classification: Class IIa

Applied Directive: Medical Device Directive (93/42/EEC)

Manufacturer: Unimicro Medical Systems (Shenzhen) Co.,Ltd.、

Address: 101, 201, 301, Bldg 38, Xialang Industrial Area, Heshuikou, Matian Street, Guangming District, Shenzhen City, Guangdong Province, 518106, P.R. China

E.U Representative Name: Wellkang Ltd

E.U Representative Address: Enterprise Hub, NW Business Complex,1 Beraghmore Rd, Derry, BT48 8SE, N. Ireland, UK

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1 General Aspects

Unimicro has obtained the CE mark for the Retrieval Pouch since Nov.11th, 2011.

1.1. Manufacturer (Legal Entity) and Contact Person

Table 1.1 the information of manufacturer

Company Name	Unimicro Medical Systems (Shenzhen) Co., Ltd.
Location	Shenzhen, China
Address	101, 201, 301, Bldg 38, Xialang Industrial Area, Heshuikou, Matian Street, Guangming District, Shenzhen City, Guangdong Province, 518106, P.R. China
Management Representative	Zuojun Liu

1.2. EU Authorized Representative

Wellkang Ltd.
Enterprise Hub, NW Business Complex,1 Beraghmore Rd, Derry, BT48 8SE, N. Ireland, UK
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Email: AuthRep@CE-marking.eu
www.CE-marking.com

1.3. Assessment Route

Annex II (excluding Section 4) to European Council Directive 93/42/EEC is chosen as the assessment procedure for the product.

1.4. Notified Body

SGS Belgium N,
Notified Body ID 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium

1.5. Device Description

The device is indicated for use in patients undergoing a laparoscopic surgical procedure. It is a single use, sterile device designed for removal of specimens during a suitable laparoscopic procedure. It is available in MEBC, MEBD, MEBS, MEBW and MEBM 5 models and in a wide range of different volume from 50mL to 1200mL.

The product consists of outer tube, inner tube, handle of outer tube, handle of inner tube, deployment assembly, drawstring thread and pouch.

1.6. Classification

The product is a short-term surgically invasive device. According to the classification criteria described in rule 7, Annex IX to the European Council Directive 93/42/EEC, this device is in Class IIa.

1.7. Facilities and Critical Subcontractors

All procedures including design, production, packaging and sterilization of the product are performed at the facilities of UNIMICRO. No critical subcontractor is involved.

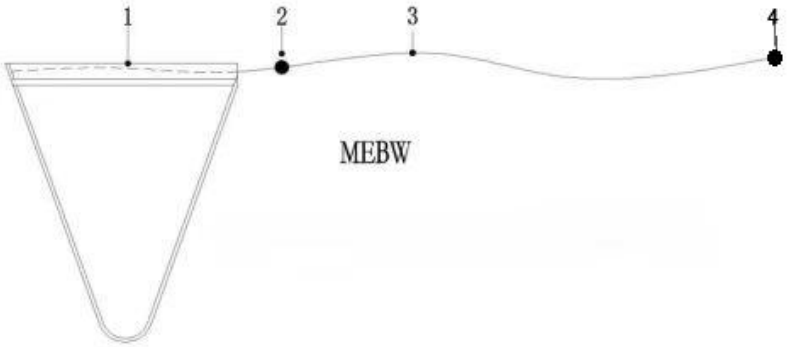
1.8. Worldwide Regulatory Status

The Retrieval Pouch received CE mark in the European Union on Nov.11th, 2011 and also received regulatory approval in China and several other foreign countries/regions. The device has been marked several years worldwide with excellent results and has no withdrawal or recall so far.

2 Device Description

2.1 General Description

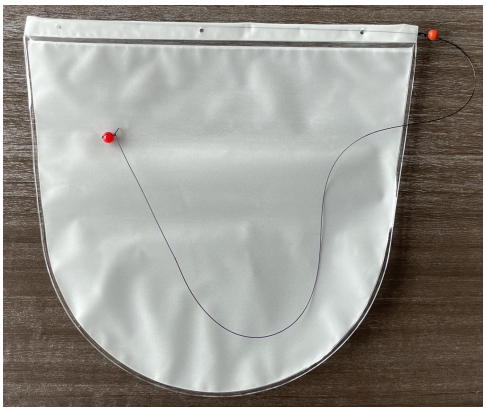
The device is indicated for use in patients undergoing a laparoscopic surgical procedure. It is a single use, sterile device designed for removal of specimens during a suitable laparoscopic procedure. See the figures below.



1- Specimen Pouch 2- Silicone Bead 3- Drawing String 4- Plastic Bead

Figure 2.1.1 Drawing of **MEBW** series

Product Image: MEBW800



2.2 Product Specification

The product specification and Model Name is specified by Volume of the Pouch. The length of the device is the same among different specifications of a model.

Device Model	Product Description	Specification Volume(ml)
MEBW200	Retrieval Pouch	200
MEBW800	Retrieval Pouch	800

2.3 Intended Use

The Retrieval Pouch is a single-use sterile bag intended to be used for collection and removal of tissue, organ and calculi from the body cavity during general and laparoscopic surgical procedures.

2.4 Indications

The Retrieval Pouch is a sterile disposable pouch used for removal of tissue specimens during a suitable laparoscopic procedure.

2.5 Intended Patient Population

The Single Use Retrieval Pouch is intended for Adults, teenagers on laparoscopic procedure. It is not intended for infants or aged higher than 70 years old, and any patient have negative medical indication against laparoscopic/endoscopic.

2.6 Contraindication

The device is not intended for use when endoscopic techniques are contraindicated.

2.7 Product Components and Materials

Disposable Retrieval Pouch consists of outer tube, inner tube, outer tube handle, inner tube handle, deployment assembly, drawstring thread and pouch.

The materials used are listed in Table 2.5.

Table 2.5 Nature of body contact and known toxicology of raw materials

Component	Materials	Nature of body contact	Duration of body contact
Specimen Pouch	TPU	Direct contact	Limited exposure within 24 hours
Drawstring Thread	PA	No Contact	Limited exposure within 24 hours
Silicone Bead	Silicone	Indirect Contact	Limited exposure within 24 hours
Plastic Bead	ABS	No Contact	Limited exposure within 24 hours

2.8 Product Dimensions

Disposable Retrieval Pouch consists of outer tube, inner tube, handle of outer tube, handle of inner tube, deployment assembly, drawstring thread and pouch.

2.9 Packaging Description

The main function of packaging is to protect the device during sterilization and transportation to ensure the device is sterile before use. The device is sterilized with EO and is single use sterile product. The protection of the packaging is validated. Three-level of packaging including primary package, secondary package and transportation package are used for the device. The device is sealed in a Tyvek1073B pouch (primary package) without coating +PET12/SPE50. Then put in the secondary package together with IFU and other accompanying files. Each secondary package contains 30 pieces. During transit, the product subjecting to secondary packaging will be put in the transport package. Each transportation package contains 600 pieces in total.

A. Primary packaging

B. Secondary packaging

C. Transportation packaging

2.10 Products Technical Specification

The product has a shelf life of three years. The details of technical specification is shown in **Table 2.8**

Table 2.8 Technical specifications of Retrieval Pouch

Item	**Requirement**
Size	The product dimensions shall meet the design requirement
Tensile strength	All junctions shall be firm with no loosening, dropping or damage and shall be able to withstand a tension force of 20N
Pouch load	The pouch shall be able to contain 1kg of weight and remain integrity
Tensile force	The drawstring thread of the pouch shall be able to hold a tensile force not less than 20N
Leak Testing	There should be no leakage after tightening the drawstring thread of the pouch containing liquid
Biocompatibility	Cytotoxicity Sensitization Irritation or intracutaneous irritation Acute Systemic Toxicity Pyrogen Toxicity
Sterilization	Sterility assurance level of 10^{-6}
Package and label	Packaging verification Stability testing (after real time aging) Compatibility with the labeling system Compatibility with the sterilization process Protection during transport and storage Maintenance of sterility No leaching of toxic substance by the packaging materials
Shelf life	Three years

3 Essential Principals and Evidence of Conformity

3.1 List of applicable standards

The list of applicable standards is combined with ER checklist and provided in **Annex I**.

3.2 Essential requirements

The essential requirement checklist is provided in **Annex I**.

3.3 Declaration of Conformity

The Declaration of Conformity is provided in **Annex II**.

3.4 Formal Statement

Unimicro hereby affirms that the Retrieval Pouch series products

- **Does not incorporate a medicinal product**
  As defined in Article 1 of Directive 65/65/EC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products.
  Nor is it intended to deliver such.
- **Does not incorporate derivatives of human blood or human plasma**
  As defined in Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 amending Council Directive 93/42/EEC as regards medical devices incorporating stable derivates of human blood or human plasma.
- **Does not incorporate or utilize any materials of animal origin**
  As defined in Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and as regulated by Directive 2003/32/EC of 23 April 2003 introducing detailed specifications as regards the requirements laid down in Council Directive93/42/EEC with respect to medical devices manufactured utilizing tissues of animal origin.
- **Does not contain phthalates**
  As defined in Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and as regulated by Directive 2007/47/EC of 21 Sept 2007 introducing detailed specifications as regards the requirements laid down in Council Directive93/42/EEC with respect to medical devices manufactured containing phthalates.

The formal statement with respect to above substances is provided in **Annex III.**

4 Risk Management

The risk management is performed by the risk management team including designers, manufacturing and testing engineers, and QA personnel during the various phases of the life time of theRetrieval Pouch according to EN ISO 14971:2019 and relevant standards.

Following the standard EN ISO 14971: 2019, the risk management group has formulated a risk management plan for the Retrieval Pouch, and the risk analysis of the device has been performed during design, manufacturing process and clinical use. All potential hazards are listed in risk management report, and the

causes of all hazards are analyzed. After evaluating the risk level, then taking and implementing some control measures, all residual risks have been successfully reduced to an acceptable level. It is concluded that the risks relating to the Retrieval Pouch are acceptable during clinical use.
The risk management file is provided in **Annex IV**.

5 Summary of Non-clinical Test

5.1. Performance

A series of performance testing items conducted on the device. The testing items includes：

- Tensile strength
- Pouch load
- Tensile force of drawstring thread
- Leak Testing

Tensile strength test result demonstrated that all junctions is firm with no loosening, dropping or damage and able to withstand a tension force of 20N. Pouch load test result shows that the pouch is able to contain 1kg of weight and remain integrity. Tensile force test result shows that the drawstring thread of the pouch is able to hold a tensile force greater than 20N. Leak test result shows no leakage after tightening the drawstring thread of the pouch containing liquid.

In addition, Unimicro conducted safety evaluation and the evaluating results demonstrated that the disposable Retrieval Pouch is safe and effective medical device.

The test reports and evaluation report are provided **in Annex V.**

5.2. Usability

The usability features of the Retrieval Pouch were evaluated by performing the usability testing to assess if the set performance meets the requirements detailed in customer needs.

The Usability Evaluation report is presented in **Annex VI**.

5.3. Package Qualification

According to EN ISO 11607, the package materials and process have been validated, including real time aging test and shelf life test. Suppliers have also provided physical and chemical specifications of package materials and inspection reports.

The Retrieval Pouch is supplied sterile. The packaging system complies with EN ISO 11607-1:2019 and EN ISO 11607-2:2019 with following data supported:

- Packaging verification
- Stability testing
- Compatibility with the labeling system
- Compatibility with the sterilization process
- Protection during transport and storage
- Maintenance of sterility
- No leaching of toxic substance by the packaging materials

The package will be subjected to the Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) procedures. The packaging system will be validated according to EN ISO 11607 and other relative standards to meet the requirements. The packaging materials are compatible with the sterilization process and labeling system and would well maintain performance characteristics under normal condition during transport and storage. It has microbial barrier properties as specified in the standards. It is not hazardous and would not adversely affect the medical device.

Equipment is delivered, installed and used in accordance with its specification. The installation qualification will utilize the heat sealer operating manual to define requirements for electrical and air pressure requirements. Installed equipment should be operated normally within predetermined limits in accordance with its operational procedures. The process parameters validated for manufacturing shall be specified. In operational qualification phase the process parameters should be challenged to assure that they would result in a product that meets all defined requirements under any anticipated conditions of manufacturing, i.e., the worst case scenario testing. Performance qualification will commence after satisfactory completion of operational qualification. The performance qualification shall demonstrate that the process, based on the process parameters established in OQ, can consistently produce acceptable sterile barrier systems under specified operating conditions. The stability of the product and the packaging system will be demonstrated by shelf life testing. Packaging process validation report, storage and transport report and stability report will be submitted. Included are materials safety file, IQ/OQ/PQ experiment record and other relative experiment record. The package qualification documentation (including IQ, OQ and PQ phases) is presented in **Annex VII.**

5.4. Sterilization

The Retrieval Pouch is sterilized with ethylene oxide (EO).
The validation is performed to demonstrate the attainment of a product sterility assurance level of 10^{-6}. The validation includes commissioning and performance qualification. EO sterilization validation reports are presented in **Annex VIII**.

5.5. Biocompatibility

The Retrieval Pouch is an externally communicating device by contact with tissue during less than 24 hours. So the following tests were performed:

- Cytotoxicity
- Sensitization
- Irritation or intracutaneous irritation
- Acute systemic toxicity
- Pyrogen

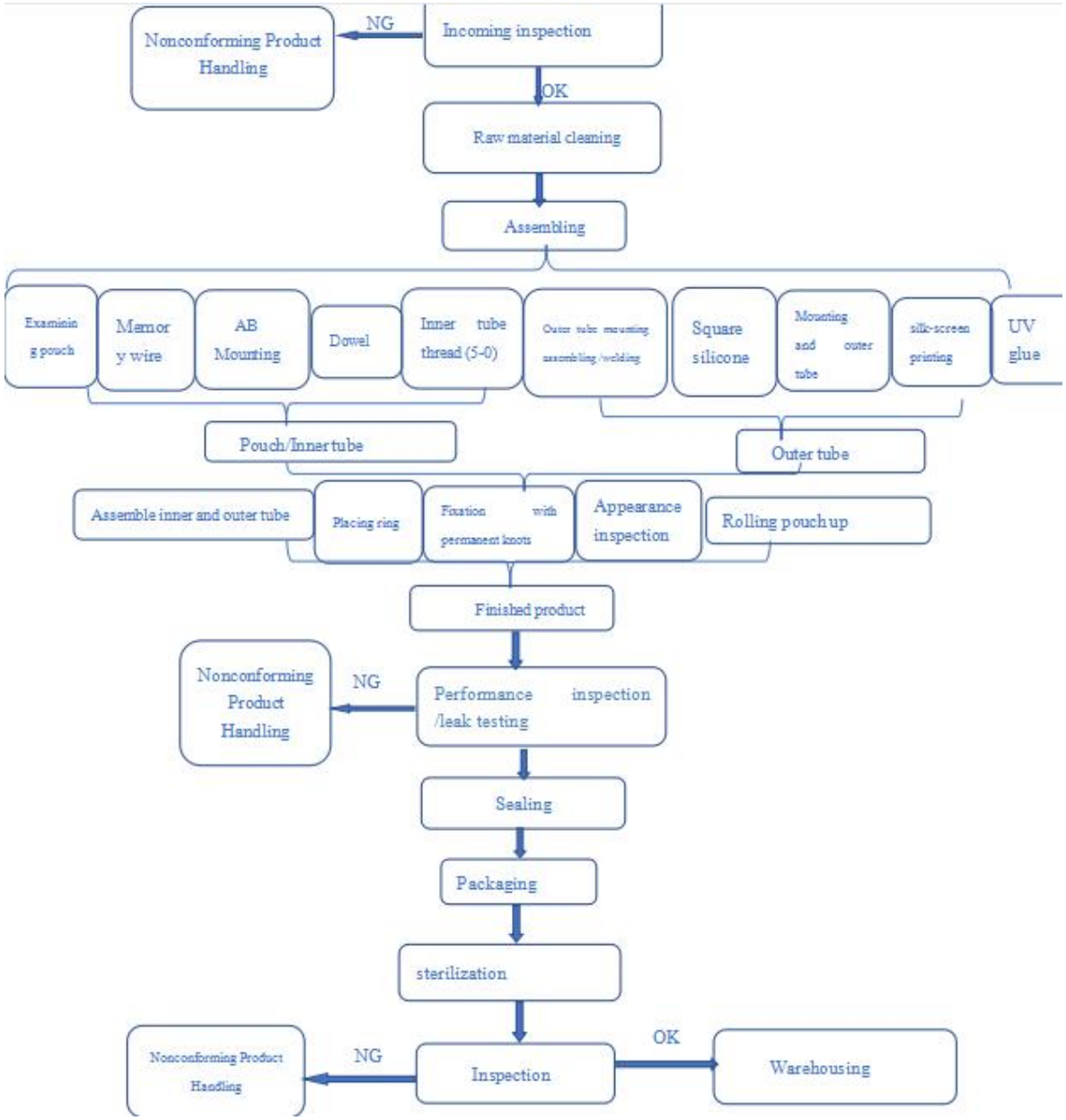
Extraction conditions for tests above shall refer to ISO10993-12.
The biocompatibility evaluation reports related to the Retrieval Pouch is presented in **Annex IX**.

5.6. Shelf life

The shelf life of the Retrieval Pouch is three years. The related shelf life test reports are presented in **Annex X**.

Manufacturing Information

The following flow chart shows the manufacturing steps of the Retrieval Pouch in accordance with established quality management system.
All manufacturing processes of the Retrieval Pouch are performed at the facility of Unimicro Medical Systems (Shenzhen) Co., Ltd.


Incoming inspection
NG
Nonconforming Product Handling
OK
Raw material cleaning
Assembling
Examining pouch
Memory wire
AB Mounting
Dowel
Inner tube thread (5-0)
Outer tube mounting assembling /welding
Square silicone
Mounting and outer tube
silk-screen printing
UV glue
Pouch/Inner tube
Outer tube
Assemble inner and outer tube
Placing ring
Fixation with permanent knots
Appearance inspection
Rolling pouch up
Finished product
Performance inspection /leak testing
NG
Nonconforming Product Handling
Sealing
Packaging
sterilization
Inspection
NG
Nonconforming Product Handling
OK
Warehousing