



# MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:  
C564964

Initial certification date:  
20 April 2023

Valid:  
20 April 2023 – 19 April 2026

This is to certify that the management system of

## **Shandong Haidike Medical Products Co., Ltd**

Tianfu Road, Dongcheng District, Shan County, 274300 Heze City, Shandong Province, China  
(Unicode: 91371722059049941D)

has been found to conform to the Quality Management System standard:  
**ISO 13485:2016**

This certificate is valid for the following scope:

**Design, Development, Manufacture, Sales and Distribution of Disposable Sterile Absorbable Surgical Sutures with or without Needle, Sterile Non Absorbable Surgical Sutures with or without Needle, Disposable Sterile or non-sterile Medical face mask and Disposable Sterile or non-sterile Medical protective clothing.**

Place and date:  
Høvik, 20 April 2023



For the issuing office:  
**DNV Product Assurance AS**  
Veritasveien 1, 1363 Høvik, Norway

*Cecilie Gudesen Torp*

**Cecilie Gudesen Torp**  
Management Representative

## Declaration of Catgut Material

Catgut is a type of thread that is prepared from the natural fibre found in the walls of animal intestines.

Catgut sutures are normally treated with chromium salt solution to resist body enzymes, to slow the absorption process, and are called catgut chromic sutures—whereas untreated catgut sutures are called catgut plain sutures.

**We**

**Shanxian Runte Medical Instruments Co., Ltd.**

**Nanduan Wenhua Road, Shan County, Heze City, Shandong, China**

***Declare that the products we are producing***

- Plain Catgut Suture
- Chromic Catgut Suture

**Are made of sheep intestine.**

**About the quality, we assure that**

- Diameter: meet the USP Standard.
- Knot pull tensile strengths: above the USP standard, at least USP standard.
- Length: pre-cut length +2-3%, not less.
- Sutures to be free of frays, folds and discolorations.



**Shanxian Runte Medical Instruments Co., LTD.**

## CATGUT

### Description

Catgut suture (Plain and Chromic) is an absorbable surgical suture composed of purified connective tissue (mostly collagen) derived from either the serosal layer of beef (bovine) or the submucosal fibrous layer of sheep (ovine) intestines.

To prepare catgut, workers clean the small intestines, free them from fat, and steep them in water. Then they scrape off the external membrane with a blunt knife, and steep the intestines again for some time in potassium hydroxide. Then they smooth and equalize the intestines by drawing them out. Lean animals yield the toughest gut. Next, they twist the prepared gut strands together to make string. String diameter is determined by the thickness of the individual guts, and by the number used. A thin string, such as USP 4/0, uses only three or four guts, whereas a double bass string may use twenty or more. After twisting and drying, workers polish the strings to the required diameter.

Catgut sutures are normally treated with chromium salt solution to resist body enzymes, to slow the absorption process, and are called catgut chromic sutures—whereas untreated catgut sutures are called catgut plain sutures.

### Characteristics

- High tensile strength
- Excellent handling properties
- Minimal tissue reaction
- Uniform absorption



### **Indication**

Surgical catgut is indicated for use in general, soft tissue approximation and/or ligation, including use in ophthalmic procedures, gastrointestinal, dental and gynecological, but not for use in cardiovascular and neurological procedures.

Plain Catgut suture should not be used where longer suture support is necessary.

Pay attention to the sensitivities or allergies to collagen or chromium.

### **Properties**

Catgut suture have a high initial tensile strength, which is retained for up to 30 days.

The process of Chromic catgut's mass absorption is completed in 90 days.

While Plain Catgut will be absorbed completely in 60-70 days.