

CIS Medical Technology (Nanjing) Co., Ltd	Document No.: DOC/CIS-01-16	Edition: D01	Date: 2026.1.16
	Sterilization Box DOC		

## DECLARATION OF CONFORMITY

### Product: Sterilization Box and Accessories

#### 1. Manufacturer Information

**Full Name:** CIS Medical Technology (Nanjing) Co., Ltd.

**Address:** No. 8 Wenzhu Road, Yuhuatai District, Nanjing City, Jiangsu Province China 210012

#### 2. Product Description

- **Product Name:** Sterilization Box and Accessories
- **Model No.:** See attachment
- **Intended Use:** For cleaning, disinfection, sterilization, storage and transportation of medical / surgical instruments under autoclave (steam sterilization).
- **Materials:** PPSU, Silicone, Aluminum Alloy 5052, Stainless Steel 304

#### 3. Statement of Conformity

We, the undersigned, as Manufacturer, hereby declare solemnly and under our responsibility that the above-mentioned product complies with the following regulations, standards and requirements:

##### International Standards:

- **ISO 14483** : Sterilization containers for medical devices
- **ISO 13485** : Quality management systems for medical devices
- **ISO 10993** : Biological evaluation of medical devices
- Material standards for PPSU, Silicone, Aluminum Alloy 5052, Stainless Steel 304

##### We confirm that:

- All technical documentation, test reports, quality system certificates and labeling are in compliance with relevant regulations.
- This Declaration of Conformity is issued under our sole responsibility.
- This declaration is valid for all batches of the same model.

#### 4. Authorization & Signature

**Legitimate Representative of Product owner**

Name: **James Huang** 黄庆高

Title: **General Manager**



*James Huang* 黄庆高



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**Attachment : List of Medical Device**

No.	Product Name	Model
1	Laparoscopic Instrument Box	LHJ-542507
2	Laparoscopic Instrument Box	LHJ-542510
3	Laparoscopic Instrument Box (2 layers)	LHJ-533015-2
4	Laparoscopic Instrument Box(2 layers)	LHJ-542510-2
5	Endoscope Box	LHJ-450804
6	Endoscope Box	LHJ-270804
7	Endoscope Box	LHJ-580804
8	Endoscope Box	LHJ-650804
9	Electric Cutting Mirror Instrument Box	LHJ-422809
10	Percutaneous Nephroscope Box	LHJ-452007
11	Cystoscope Instrument Box (2 layers)	LHJ-532309-2
12	Electric Uterine Cutting Instrument Box (3 layers)	LHJ-552513-3
13	Laryngoscope Instrument Box (2 layers)	LHJ-432109-2
14	Sinoscope Instrument Box (3 layers)	LHJ-362609-3
15	Universal Box	LHJ-302005
16	Universal Box	LHJ-302007
17	Universal Box (2 layers)	LHJ-302009-2
18	Microscope Box with Silicone Pad	LHJ-251602
19	Microscope Box with Silicone Pad	LHJ-261603
20	Microscope Box with Silicone Pad (2 layers)	LHJ-261604-2
21	Microscope Box with Silicone Bracket	LHJ-252505
22	Microscope Box with Silicone Bracket	LHJ-271206
23	Microscope Box with Silicone Bracket	LHJ-252507

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24	Microscope Box with Silicone Bracket	LHJ-372305
25	Microscope Box with Silicone Bracket	LHJ-372307
26	Microscope Box with Silicone Bracket (2 layers)	LHJ-252510-2
27	Flexible Choledochoscope Box	LHJ-603010
28	Complete Set of Intervertebral Foramen Mirror Apparatus (3 layers)	LHJ-542513-3
29	Intervertebral Foraminal Endoscope Box	LHJ-361307
30	Hysteroscope Box	LHJ-401407
31	Universal Instrument Box	LHJ-602505
32	Universal Instrument Box	LHJ-602510
33	Ureteroscope Box	LHJ-601408
34	Ureteroscope Box	LHJ-661408
35	Ureteroscope Box	LHJ-701408
36	Ureteroscope Box	LHJ-732010
37	Arthroscopic Instrument Box (2 layers)	LHJ-432514-2
38	PPSU Endoscope Box	PPSU-450704
39	PPSU Endoscope Box	PPSU-270704
40	PPSU Microscope Box with Silicone Pad	PPSU-221402
41	PPSU Microscope Box with Silicone Pad	PPSU-160902
42	PPSU Microscope Box with Silicone Pad	PPSU-261602
43	PPSU Microscope Box with Silicone Pad (2 layers)	PPSU-261504-2
44	Silicone Resin Endoscope Box (white)	GSZ-321006
45	Silicone Resin Endoscope Box (white)	GSZ-461006
46	Stainless Steel Basket	BXG-270905
47	Stainless Steel Basket	BXG-450905



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48	Silicone Pad	SP-3020
49	Silicone Pad	SP-5425
50	Silicone Pad	SP-6030
51	Silicone Pad	SP-7648
52	Silicone Slot Strip	SST-230
53	Silicone Slot Strip	SST-075

