

1. Company administrative information				
Review date: 2024-10				
1.1	Name: Delmont imaging			
1.2	Complete adress: 390 Avenue du Mistral 13600 La Ciotat, FRANCE		Tel: 09 51 51 30 30 Fax: 09 57 51 31 00 e-mail: contact@delmont-imaging.com Website: www.delmont-imaging.com	
1.3	Materialovigilance contact details: Robin GREFFEUILLE		Tel: 04 22 22 00 13 Fax: 09 57 51 31 00 e-mail: vigilance@delmont-imaging.com	
2. Device or equipment information				
2.1	Common name: HD endoscopic camera			
2.2	Commercial name: iSee			
2.3	Nomenclature code: N/A			
2.4	Medical device class: I Conformity: Conform to European regulation 2017/745 Date first marketed in the EU: 2024 Medical device manufacturer: Delmont imaging			
2.5	Device description: iSee is an endoscopic video camera designed for use by qualified surgeons during surgical endoscopies or diagnostic procedures.			
2.6	Catalog references:			
	Article reference	GTIN/UID-ID code	Specification	Packaging
	D100 100 020	03701217807167	Control unit: (See image a.) <ul style="list-style-type: none">Dimensions: Width: 310 mm, Height: 75 mm, Depth: 310 mm.Weight: 3,5 kgDescription: Front side: 1 output for connecting the endoscopic camera, 1 USB storage key. Lateral left side: 1 aeration grid. Lateral right side: 1 standby button Bottom side: 1 aeration grid, 4 feet.	1

Article reference	GTIN/IUD-ID code	Specification	Packaging
		<p>Back side: 1 main power switch, 1 output for IEC 60320 C13 power supply, 1 equipotential plug, 1 3G-SDI output, 2 HDMI outputs.</p> <ul style="list-style-type: none"> Power supply: 100-230 V AC, 50/60 Hz, power consumption: 40 VA, fuses: 2 T2A - 250 V UL/CSA 5 x 20 mm. Available languages: 14 (French, German, English, Danish, Spanish, Finnish, Greek, Italian, Norwegian, Dutch, Portuguese, Russian, Swedish and Chinese). Image settings: brightness (10 levels), saturation (10 levels), contours (10 levels), gamma (10 levels), red gain (10 levels), blue gain (10 levels), anti-moiré (active/inactive). Accessories included: 1 power cable (See image c.), 1 USB key (See image d.), 1 HDMI cable (See image e.). 	
D100 110 000	03701217800014	<p>Camera head without objective: (See image b.)</p> <ul style="list-style-type: none"> Camera sensor weight: 260 g. Camera cable length: 2,3 m. Objective connection: C-mount. Description: 3 buttons programmed by default on the camera head allowing white balance, taking photos, video recordings, digital zoom. Has protection IPX7. Sensor type: HD CMOS 1/3". Electronic shutter: Automatic (1/50 to 1/10 000). Image quality: resolution 1920x1080, progressive scanning, definition > 900 lines, sensibility 2000 lux at F8, S/B ratio: 54 dB. 	1
<p>Kit: No Labelling: Refer to appendix.</p>			

2.7	<p>Device and accessories composition:</p> <ul style="list-style-type: none"> Housing materials: Aluminium, glass. Foot material: RMS-190 Neoprene rubber. Camera head materials: Aluminium, silicone. <p>Latex free. Phthalates free. Absence of active substances. Absence of products of animal or biological origin.</p> <p>Related devices and accessories: D100 120 000 Focal lens F=22mm (See image f). D100 120 001 Focal lens F=18mm (See image f). D100 120 002 Focal zoom lens (F =16 to 34mm) (See image g). D200 110 000 Neovo 22" screen, with optical glass. Full HD resolution (See image h). D200 110 001 Neovo 22" screen, medical grade, with optical glass. Full HD resolution (See image h). D200 110 003 Neovo 24" screen. Full HD resolution (See image h). D200 110 004 Neovo 24", medical grade. Full HD resolution (See image h).</p>
2.8	<p>Application: Endoscopy examinations or diagnostic procedures. Intended use: The device is indicated for use by a healthcare professional in diagnostic and operative endoscopic procedures in a healthcare facility equipped with an appropriate setup.</p>

3. Sterilization process

Medical device supplied sterile: No
Device sterilization mode: Non-sterilizable. Submersible camera head.
Is this medical device indicated/used in neonates : No
Is this medical device indicated/used in premature newborns : No
Is this medical device indicated/used in infants : No

4. Storage conditions

Storage conditions: Room temperature: -10°C to +40°C / Relative humidity: 20% to 85%, without condensation/
Avoid direct sunlight. Atmospheric pressure: 800 hPa to 1 060 hPa.
Expiry date: The storage time of the device is not limited.







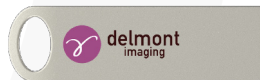

5. Safety in use

- | | |
|-----|---|
| 5.1 | Technical safety: Comply to the user manual. |
| 5.2 | Biological safety: N/A |

6. Directions for use	
6.1	Instructions for use : Refer to the operating instructions.
6.2	Indications : Refer to the operating instructions.
6.3	Precautions for use : Refer to the operating instructions.
6.4	Contraindications : Refer to the operating instructions.

7. Product additional informations	
	N/A

8. List of appendices	
	<ul style="list-style-type: none"> - Labelling and traceability label (if applicable) - User manual (D900 700 037)

9. Images			
a.		e.	
b.		f.	
c.		g.	
d.		h.	

delmont imaging

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