

1. Company administrative information				
Review date: 2024-10				
1.1	Name: Delmont imaging			
1.2	Complete address: 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: Light source for endoscopic procedures			
2.2	Commercial name: iLight			
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: iLight is a LED light source designed for use by qualified surgeons in surgical endoscopies and diagnostic procedures.			
2.6	Catalog references:			
	Article reference	GTIN/UID-ID code	Specification	Packaging
	D100 100 040	03701217807174	Light source control unit: (See image a.) <ul style="list-style-type: none">Dimensions: width: 310 mm, height: 75 mm, depth: 310 mm.Weight: 3,8 kg.Light source: Life-time expectancy of the LED: 50 000 hours, intensity equivalent to a 300 watt xenon light source, color temperature: 6500K, CRI (color rendering index) >70.	1

Article reference	GTIN/UID-ID code	Specification	Packaging
		<ul style="list-style-type: none"> Description: Front side: 1 Storz compatible light cable plug, 1 screen of 1.4 x 6.2mm which allows the user to visualize the different phases of product use. Lateral left side: 1 aeration grid. Lateral right side: 1 standby button et 2 buttons «+» and «-» for brightness adjustment (10 intensity levels). Back side: 1 aeration grid, 1 main power switch, 1 IEC 60320 C13 power supply output, 1 equipotential plug. Bottom side: 1 aeration grid, 4 foot. Power supply: 100-230 V AC, 50/60 Hz, power consumption: 230 VA, fuses: 2 T2A - 250 V UL/CSA 5 x 20 mm. Safety: Light cable detection system, automatic thermal protection. Accessories included: 1 power cable (See image b). 	
Kit: No Labelling: Refer to appendix.			
2.7	Device and accessories composition: <ul style="list-style-type: none"> Housing materials: Aluminium, glass. Foot material: Neoprene RMS-190 rubber. <p>Latex-free. Phtalates-free. Absence of active substances. Absence of products of animal or biological origin.</p> <p>Related devices and accessories: D200 150 000 Light cable, grey, Ø: 3.5mm, L: 2.3m. (See image c). D200 150 005 Light cable, grey, Ø: 4,8mm, L: 2,3m. (See image c) D200 150 001 Storz connector to the light cable - Endoscope side. (See image d). D200 150 002 Storz connector to the light cable - Light source side. (See image e).</p>		
2.8	Application: Endoscopic examinations or diagnostic procedures. Intended use: The device is indicated for use by a healthcare professional for endoscopic diagnostic and operative procedures in an appropriately configured healthcare facility.		

3. Sterilization process

Medical device supplied sterile: No
Device sterilization mode: Non-sterilizable.
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%, condensation free.
 Avoid direct sunlight. Atmospheric pressure: 800 hPa to 1 060 hPa.
Expiry date: Non-sterile devices can be stored for any length of time.

5. Safety in use

- 5.1 **Technical safety:** Refer to the operating instructions.
 5.2 **Biological safety:** N/A

6. Directions for use

- 6.1 **Instructions for use:** Refer to the operating instructions.
 6.2 **Indications:** See section 2.9
 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

- Labelling and traceability label (if applicable)
- User manual (D900 700 036)

9. Images

a.



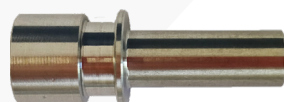
b.



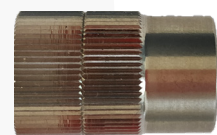
c.



d.



e.



delmont imaging

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