

1. Company administrative information			
Review date: 2023-12-08			
1.1	Name: Delmont imaging		
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2. Device or equipment information			
2.1	Common name: Hysteroscopy system		
2.2	Commercial name: EasyCare		
2.3	Nomenclature code: N/A		
2.4	Medical device class: IIa Conformity: Conform to MDD 93/42/CEE Notified body number: 1304 Date first marketed in the EU: 2017 Medical device manufacturer: Delmont imaging		
2.5	Device description: Hysteroscopy system for direct visualization of the interior of the uterine cavity. Surgical sheaths and instruments allow treatment of intrauterine pathologies without using energy.		
2.6	Catalog references:		
	Hysteroscope		
	Article reference	GTIN/UID ID code	Specification
	D300 100 000	03701217800168	Hysteroscope (Photo a) - Dimensions: External diameter 2.9 mm, working length : 300 mm, total length : 395 mm. - Description: Endoscope with HD resolution lenses, 30° distal angulation and insert for connection to ACMI-type light cable. - Included accessories: 2 light cable adapters : Storz and Olympus type, polishing paste, protective tube for endoscope.
			Packaging 1

Hysteroscope sheaths			
Article reference	GTIN/UID ID code	Specification	Packaging
D300 110 002	03701217800632	Diagnostic sheath (Photo b) Dimensions: External diameter 4 mm, working length: 270 mm, total length : 310 mm. Description: Centimetric scale, rotatable irrigation stopcock, bayonet connection with hysteroscope.	1
D300 110 000	03701217800618	Outer operating sheath (Photo c) Dimensions: External diameter : 5,5 mm, working length : 216 mm, total length : 250 mm. Description: Centimetric scale, rotatable suction stopcock, «Quick-lock» connection with hysteroscope, atraumatic distal tip.	1
D300 110 001	03701217800625	Inner operating sheath (Photo d) Dimensions: External diameter: 4,9 mm, operative canal's diameter: 7Fr, working length: 230 mm, total length: 310 mm with insertion canal's length of 50 mm. Description: Centimetric scale, rotatable irrigation stopcock, bayonet connection with hysteroscope, atraumatic distal tip.	1
Instruments			
With rotation module			
Article reference	GTIN/UID ID code	Specification	Packaging
D300 120 065	03701217807433	Semi-rigid sharp (Photo e.1) Dimensions: Diameter 7Fr., working length : 370 mm, total length : 480 mm. Description: Graduations on the distal shaft, 1 mobile jaw, rotatable, rod can be detached from handle via «Quick-lock» connection, flushing port (Luer-lock connexion).	1
D300 120 066	03701217807426	Semi-rigid blunted sharp (Photo e.2) Dimensions : Diameter 7Fr., working length: 370 mm, total length: 480 mm. Description: Graduations on the distal shaft, 1 mobile jaw, rotatable, rod can be detached from handle via «Quick-lock» connection, flushing port (Luer-lock connexion).	1

Article reference	GTIN/UID ID code	Specification	Packaging
D300 120 068	03701217807402	Semi-rigid forceps (alligator) (Photo e.3) Dimensions: Diameter 7Fr., working length: 370 mm, total length: 480 mm. Description: Graduations on the distal shaft, 2 mobile jaws, rotatable, rod can be detached from handle via «Quick-lock» connection, flushing port (Luer-lock connexion).	1
D300 120 067	03701217807419	Semi-rigid biopsy forceps (Photo e.4) Dimensions: Diameter 7Fr., working length: 370 mm, total length: 480 mm. Description: Graduations on the distal shaft, 2 mobile jaws, rotatable, rod can be detached from handle via «Quick-lock» connection, flushing port (Luer-lock connexion).	1
D300 120 069	03701217807396	Semi-rigid IUD grasping forceps (Photo e.5) Dimensions: Diameter 7Fr., working length: 370 mm, total length: 480 mm. Description: Graduations on the distal shaft, 2 mobile jaws, rotatable, rod can be detached from handle via «Quick-lock» connection, flushing port (Luer-lock connexion).	1
Without rotation module			
D300 120 000	03701217801196	Semi-rigid sharp (Photo f.1) Dimensions: Diameter 7Fr., working length: 340 mm, total length: 445 mm. Description: Graduations on the distal shaft, 1 mobile jaw, rod can be detached from handle and the handle is detachable in 2 parts, without flushing port.	1
D300 120 001	03701217801202	Semi-rigid forceps (alligator) (Photo f.2) Dimensions : Diameter 7Fr., working length : 340 mm, total length : 445 mm. Description : Graduations on the distal shaft, 2 mobile jaws, rod can be detached from handle and the handle is detachable in 2 parts, without flushing port.	1
D300 120 002	03701217801219	Semi-rigid biopsy forceps (voir image f.3) Dimensions: Diameter 7Fr., working length: 340 mm, total length: 445 mm. Description: Graduations on the distal shaft, 2 mobile jaws, rod can be detached from handle and the handle is detachable in 2 parts, without flushing port.	1

Article reference	GTIN/UID ID code	Specification	Packaging
D300 120 003	03701217801226	Semi-rigid IUD grasping forceps (Photo f.4) Dimensions: Diameter 7Fr., working length: 340 mm, total length: 445 mm. Description: Graduations on the distal shaft, 2 mobile jaws, rod can be detached from handle and the handle is detachable in 2 parts, without flushing port.	1
Light cable			
D200 150 500	03701217800090	Grey light cable (Photo g) Dimensions: Diameter: 3,5 mm, length: 2,3 m. Description: Unscrewable end caps on both sides, supplied with Storz end caps. Device class: I	1
Sterilization basket			
D200 160 522	03701217802605	EasyCare set sterilization basket (Photo k) Dimensions: 540x240x70mm. Description: Personalized silicone holders for EasyCare set. Device class: I	1
2.7	Device and accessories composition : - Sleeve materials: Tube: stainless steel (1.4301) Valve: stainless steel (1.4305) Plastic components: polyphenylsulfone (PPSU) - Instrument materials: Stem: stainless steel (1.4301) Handle and jaws: stainless steel (1. 4321) Rod and jaw joint: stainless steel (1.4310) Rotation module: Aluminium (AlMgSi 0.5/AlMgSi 1.0) - Hysteroscope materials: Outer tube: stainless steel (304) Inner tube: glass fiber Tube tip: sapphire Light cable connection insert: stainless steel (303) Light cable connection insert interior: optical glass Wand: polyetheretherketone (PEEK) - Light cable materials: End caps: stainless steel (1.4305) Outer sheath: silicone Black handle: PPSU plastic Fiber: optical glass Latex free. DEHP free. Halogen free. No products of animal or biological origin. Related devices and accessories : D300 140 011 Bipolar electrode, flexible, needle type, 5Fr., working length: 360mm. Photo h. D300 140 010 Bipolar electrode, flexible, button type 5Fr., working length: 360mm. Photo i. D300 140 038 Bipolar electrode, flexible, curved needle type, 5Fr., working length: 360mm. Photo j. <i>These instruments have their own data sheet.</i>		

2.8	Application: Surgery Intended use: The hysteroscopy system is an invasive and accessory active medical device. It is intended for use with a hysteroscope for examination and surgical treatment of the cervical canal and uterine cavity.
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3. Sterilization process

Medical device supplied sterile : No
Device sterilization mode: Autoclave (See Instructions for Use for more details)
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 : Ambient temperature : 10°C à 35°C / Relative humidity: 10% à 85%, condensation free/
 Avoid direct sunlight.
Special precautions : Non-sterile devices must be stored in a clean, dry environment.
Expiry date : Non-sterile devices can be stored for any length of time.

5. Safety in use

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| 5.1 | Technical safety : Follow the operating instructions. |
| 5.2 | Biological safety: N/A |

6. Directions for use

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| 6.1 | Instructions for use : Follow the operating instructions. |
| 6.2 | Indications : Diagnostic and operative endoscopic procedures by a healthcare professional for the medical field of hysteroscopy in a health center equipped with an appropriate endoscopic configuration, in the case of :
-Pelvic pain
- Abnormal uterine bleeding
- Amenorrhea
- Directed biopsy
- Sterile removal
- Evaluation of abnormal hysterosalpingography
- Trophoblastic retention
- Intrauterine foreign body
- Polyp or fibroid removal
- Septum removal
- Synechia sectioning |
| 6.3 | Precautions for use : Follow the operating instructions. |
| 6.4 | Contraindications : Follow the instructions. |

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SAS au capital de 252 400 euros - RCS Marseille 817 710 411 - N° de TVA Intracommunautaire : FR 81 817 710 411

7. List of appendices

- Labelling and traceability label (if applicable)
- Leaflet (D900 700 002)
- User manual (D900 700 026/D900 700 023/D900 700 034/D900 700 035)
- CE certificate

8. Photo

