

1. Company administrative information			
Review date: 2024-06			
1.1	Name: Delmont imaging		
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2. Device or equipment information			
2.1	Common name: Hysteroscopy system		
2.2	Commercial name: NeoCare (Photo a.)		
2.3	Nomenclature code: N/A		
2.4	Medical device class:IIb Conformity: 93/42 according to the appendix II Notified body number: 1304 Date first marketed in the EU: 2021 Medical device manufacturer: Delmont imaging		
2.5	Device description: Hysteroscopy system for visualising the inside of the uterine cavity. The surgical sheath, instruments and electrodes enable intrauterine pathology to be treated.		
2.6	Catalog references:		
	Hysteroscope		
	Article reference	GTIN/UID ID code	Specification
	D100 300 049	03701217806115	Operating hysteroscope: (Photo b.) - Description: 45° deported optics, HD resolution lenses, 12° distal angulation, working length: 192mm, total length: 330mm, operative canal's diameter: 3,33mm and operative canal's length: 290mm, rotation module for rotation in relation to the sleeve and insert for connection toACMI-type light cable. 2 light cable adapters: Storz, Olympus. - Medical device class: IIa.
			Packaging
			1
Sheath			
D300 130 000	03701217801271	External double flow sheath: (Photo c.) - Dimensions: working length: 183mm, external diameter: 6,5mm, total length: 207mm. - Description: «Quick-lock» connection with hysteroscope, centimetric scale, 1 rotatable irrigation stopcock and 1 rotatable suction stopcock - Medical device class: IIb.	1

Instruments			
Handle for 3mm inserts			
Article reference	GTIN/UID ID code	Specification	Packaging
D300 120 553	03701217805545	Plastic handle for 3mm inserts: (Photo d.) Description: total length: 136mm, 1 rotation module, screw-type connection with insert, without rack. Medical device class: I.	1
3mm inserts			
D300 120 509	03701217805149	Straight microscissors 3mm: (Photo e.1) Dimensions : working length: 330mm, total length: 370mm, diameter: 3mm. Description : 1 mobile jaws of length: 6mm , flushing port (Luer-lock connexion), rigid insert. Medical device class: IIb.	1
D300 120 507	03701217805163	Curved scissors, Metzenbaum type 3mm: (Photo e.2) Dimensions: working length: 330 mm, total length: 395mm, diameter: 3mm. Description : 2 mobile jaws of length: 12mm, flushing port (Luer-lock connexion), rigid insert. Medical device class: IIb.	1
D300 120 510	03701217805132	Universal gripping forceps 3mm: (Photo e.3) Dimensions: working length: 330mm, total length: 386mm, diameter: 3mm. Description: 2 mobile jaws of length: 18mm, flushing port (Luer-lock connexion), rigid insert. Medical device class: IIb.	1
D300 120 515	03701217805088	2x3 teeth gripping and extraction forceps 3mm: (Photo e.4) Dimensions: working length: 330mm, total length: 390mm, diameter: 3mm. Descriptio : 1 mobile jaws of length: 11mm, flushing port (Luer-lock connexion), rigid insert. Medical device class: IIb.	1
3mm bipolar electrodes			
D300 140 133	03701217803732	Bipolar L-hook electrode (Photo f.1) Dimensions and description: total length: 420mm, working length: 340mm, diameter: 3mm, rigid stem, bipolar square flat connector insert. Medical device class: IIb.	1

Article reference	GTIN/UID ID code	Specification	Packaging
D300 140 134	03701217803749	Bipolar ball electrode: (Photo f.2) Dimensions and description: total length: 420mm, working length: 340mm, diameter: 3mm, rigid stem, bipolar square flat connector insert. Medical device class: IIb.	1
D300 140 135	03701217803756	Bipolar V-shape electrode: (Photo f.3) Dimensions and description: total length: 420mm, working length: 340mm, diameter: 3mm, rigid stem, bipolar square flat connector insert. Medical device class: IIb.	1
Light cable			
D100 200 114	03701217807877	Grey light cable: (Photo g.) Dimensions : Diameter: 3,5mm, length: 2,3m. Description: Unscrewable end caps on both sides,- supplied with Storz end caps. Medical device class: I	1
Sterilization basket			
D200 160 521	03701217802667	NeoCare set sterilization basket: (Photo h.1) Description: 1 cover and 2 trays with personalized silicone holders for NeoCare. Stackable trays thanks to side connections. Basket dimensions: 520x50x255mm. Tray weight: 1,9 kg. Total basket dimensions: 535x110x255mm. Total tray weight: 4,6 kg. Medical device class: I	1
TKit: No. Labelling: See appendix.			
2.8	Composition du dispositif et accessoires : Handle materials: Stainless steel (1.4305 et 1.4021) Black polyamide (PA6.6GF30) Inserts materials: Stainless steel(1.4021, 1.4301, 1.4305 et 1.4310) Plastic (PPSU) Light cable materials: Optical fiber: glass Metal connectors: stainless steel (1.4305) Handle: plastic (PPSU) Protective sheath: silicone Sterilisation basket materials: Tray: acier inoxydable (1.4305) Supports: black silicone		
	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) Electrodes materials: Connection tip: stainless steel (1.4310) and PEEK polymer Handle: plastic (black PPSU) Isolating ring between stem and instrument : White PTFE Outer tube: PVDF Tip: stainless steel (ball: 1.4307, L-hook and V-hook: 1.431)		

Latex free.
DEHP free.
Halogen free.
No products of animal or biological origin.

Related devices and accessories:

D200 160 517 MiniCare sterilization basket - ReseCare tray. (Photo h.2)
D300 195 003 MiniCare single-use internal valves - sterile. (Photo i.)
D200 190 020 iSpark bipolar HF cable, flat square plug. (Photo j.)
D300 120 506 3mm straight scissors, Metzenbaum type, double action jaws. (Photo k.1)
D300 120 508 3mm hook scissors, single action jaws. (Photo k.2)
D300 120 511 NeoCare sterilization basket - operative hysteroscope tray. (Photo l.1)
D300 120 512 3mm dissecting forceps, fenestred, double action jaws. (Photo l.2)
D300 120 513 3mm dolphin grasping forceps, double action jaws. (Photo l.3)
D300 120 514 3mm sharp grasping forceps, with crosswise teeth, double action jaws. (Photo l.4)
D300 120 516 3mm biopsy forceps, double action jaws. (Photo l.5)
D300 120 520 3mm blunt grasping forceps with reservoir, double action jaws. (Photo l.6)
D300 120 626 Ø3mm myom driller, working length: 330mm.(Photo m.)
D300 195 004 NeoCare hysteroscope sealing tap and sealing cap. (Photo n.)
D300 195 000 Reusable sealing cap for operative sheath.(Photo o.)

- 2.9 **Application:** Surgery
Intended use: The hysteroscopy system is a medical device, accessory active, invasive, intended to be used with a hysteroscope for the examination and surgical treatment of the cervical canal and uterine cavity.

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. Atmospheric pressure: 700 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:** Follow the operating instructions.
 5.2 **Biological safety:** N/A

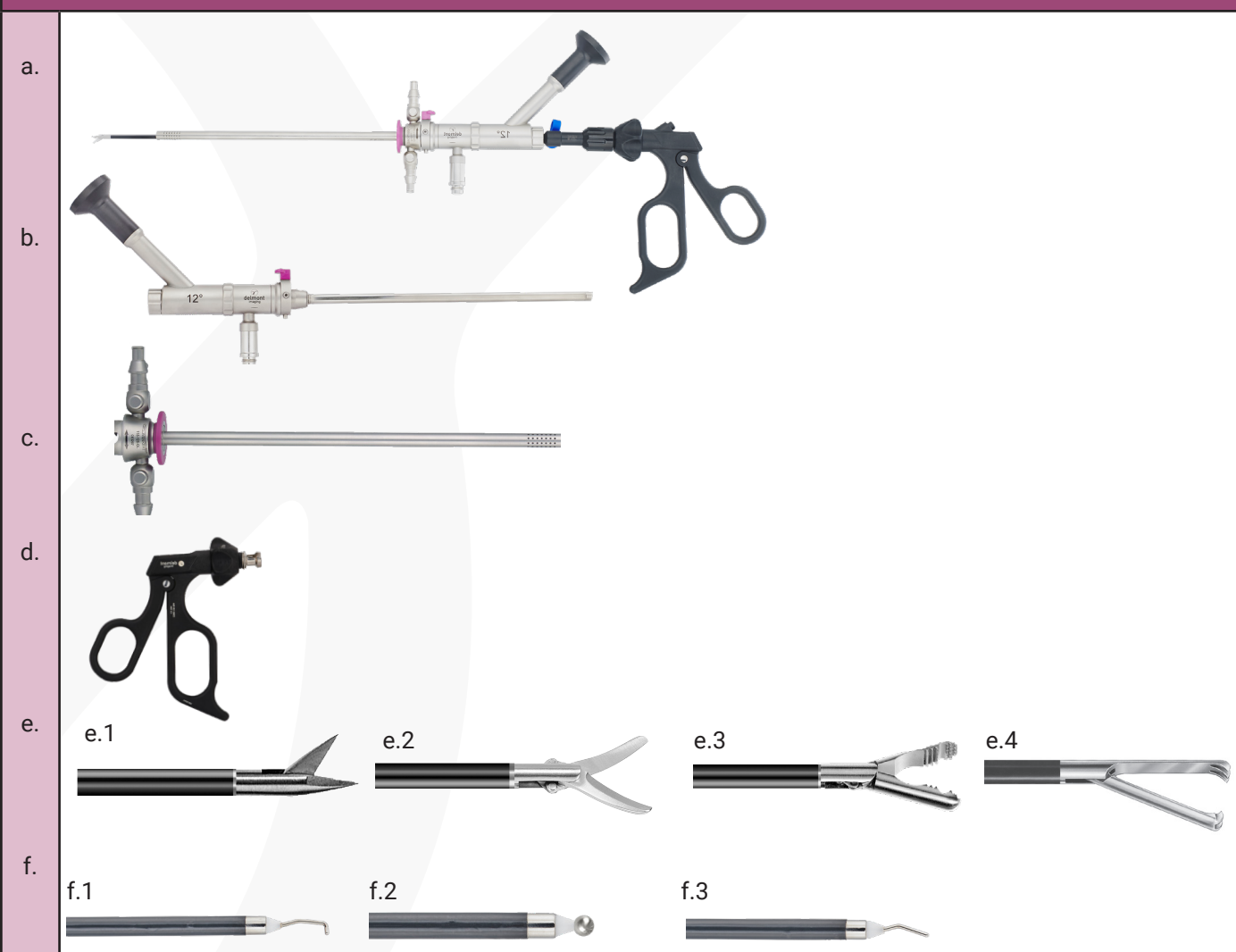
6. Directions for use

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|-----|--|
| 6.1 | Instructions for use : Follow the operating instructions. |
| 6.2 | Indications: follow 2.9. |
| 6.3 | Precautions for use: Follow the operating instructions. |
| 6.4 | Contraindications: Follow the operating instructions. |

7. List of appendices

- Labelling and traceability label
- Leaflet(D900 700 192).
- User manual (Hysteroscope: D900 700 023/ electrodes: D900 700 074/ mini-invasive instruments:D900 700 076)
- CE certificate

8. Photo



8. Photo

g.

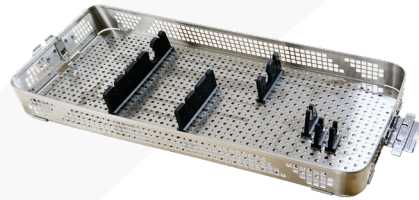


h.

h.1



h.2



i.



j.



k.

k.1



k.2



l.

l.1



l.2



l.3



l.4



l.5



l.6



m.



n.



o.



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