

1. Company administrative information Review date: 2024-01			
1.1	<b>Name:</b> Delmont imaging		
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1.3	<b>Materialovigilance contact details:</b> Robin GREFFEUILLE	<b>Tel:</b> 04 22 22 00 13 <b>Fax:</b> 09 57 51 31 00 <b>email:</b> vigilance@delmont-imaging.com	
2. Device or equipment information			
2.1	<b>Common name:</b> Camera for colposcopes		
2.2	<b>Commercial name:</b> iCare mini		
2.3	<b>Nomenclature code:</b> N/A		
2.4	<b>Medical device class:</b> I <b>Conformity:</b> Regulation (EU) 2017/745 <b>Date first marketed in the EU:</b> 2024 <b>Medical device manufacturer:</b> Delmont imaging		
2.5	<b>Device description:</b> iCare mini is an externally powered device which, when used with an appropriate colposcope, is designed to provide additional digital visualization of the colposcope image. It includes image and video recording functions. However, the device has no diagnostic function.		
2.6	<b>Catalog references:</b>		
	<b>Camera</b>		
	Article reference	GTIN/UID ID code	Specification
D100 300 550	03701217803060	<b>Camera for colposcopes:</b> (Photo a.) <ul style="list-style-type: none"> <li><b>Dimensions:</b> Width: 80 mm, height: 80 mm, depth: 56 mm.</li> <li><b>Weight:</b> 0.550 kg.</li> <li><b>Power supply:</b> 12VDC 6W, medical-certified external power adapter (Photo b.5).</li> <li><b>Description:</b> CS camera mount, HD CMOS 4Mpixel sensor, automatic electronic shutter (1/50 to 1/75,000).</li> </ul>	1

Article reference	GTIN/UID ID code	Specification	Packaging
D100 300 550	03701217803060	<ul style="list-style-type: none"> <li>• <b>Wi-Fi settings:</b> Wi-Fi WLAN standard IEEE 802.11a/n (5 GHz) 2x2 MU-MIMO, WPA2 encryption.</li> <li>• <b>Button action:</b> <ul style="list-style-type: none"> <li>- Stand by button: start/stop exam.</li> <li>Out of exam: <ul style="list-style-type: none"> <li>- Right button short press: right-hand navigation.</li> <li>- Left button short press: left-hand navigation.</li> <li>- Middle button short press: validation.</li> </ul> </li> <li>During examination: <ul style="list-style-type: none"> <li>- Middle button short press: take photo.</li> <li>- Middle button long press: video recording.</li> <li>- Right button long press: preview photos of current exam.</li> <li>- Right button short press: freeze image on screen.</li> <li>- Left button long press: white balance.</li> </ul> </li> </ul> </li> <li>• <b>Additional features:</b> <ul style="list-style-type: none"> <li>- Allows you to delete the contents of the USB stick via the iCare mini settings menu.</li> <li>- Video stream sharing via Wi-Fi.</li> <li>- Connection to the care center via Wi-Fi or Ethernet.</li> <li>- Interoperability.</li> </ul> </li> <li>• <b>Connectors:</b> 1 micro HDMI video output, 2 USB outputs (one for the USB storage key, the other for the WIFI key), one 5mm jack input for power supply.</li> <li>• <b>Image parameters:</b> Adjustment of brightness, saturation, sharpness, gamma, red gain and blue gain.</li> <li>• <b>Resolution :</b> video: 1920 x 1080p , photo: 2688x1520.</li> <li>• <b>Available languages:</b> 14 (French, German, English, Danish, Spanish, Finnish, Greek, Italian, Norwegian, Dutch, Portuguese, Russian, Swedish and Chinese).</li> <li>• <b>Update:</b> If there's an Internet connection, automatic alert and update to install. If not, update installed via USB key.</li> <li>• <b>Supplied accessories:</b> 1 USB storage key (Photo b.1), 1 WIFI key (Photo b.2), 1 CS to C mount adapter ring (Photo b.3), 1 micro HDMI to HDMI cable (Photo b.4), and 1 power supply unit (Photo b.5).</li> </ul>	

Article reference	GTIN/UID ID code	Specification	Packaging
<b>iPad Pro</b>			
D100 200 500	3701217806092	<b>iPad Pro to use imagyn:</b> (Photo c.) <ul style="list-style-type: none"> <li>• <b>Dimensions:</b> Width: 214.9 mm, height: 6.4 mm, depth: 280.6 mm.</li> <li>• <b>Screen size:</b> 12.9".</li> <li>• <b>Resolution:</b> 2 732 x 2 048.</li> <li>• <b>Storage capacity:</b> 256 Go.</li> <li>• <b>Description:</b> iCare mini connection via Wi-Fi.</li> <li>• <b>Supplied accessories:</b> Keyboard and Apple stylus.</li> <li>• <b>Color :</b> Silver.</li> </ul>	1
<b>Licence imagyn</b>			
D100 200 114	03701217807877	<b>Colposcopy license:</b> (Photo d.) <ul style="list-style-type: none"> <li>• <b>Description:</b> Visualization of the medical examination and edition of the colposcopy report</li> <li>• <b>Functionalities :</b> <ul style="list-style-type: none"> <li>- Allows annotation of photos and sketches.</li> <li>- Security when modifying an examination: draft function recovers data from an unfinished report (manual abandonment, technical malfunction).</li> <li>- Report entry within the application, followed by export/print.</li> <li>- Possibility of completing the report if biopsy results are obtained later</li> <li>- Permits management of personal space for doctors, record patient files, examination reports and care center form.</li> <li>- Interoperability.</li> </ul> </li> <li>• <b>Availability:</b> On the AppStore.</li> <li>• <b>Available languages:</b> 13 (French, German, English, Danish, Spanish, Finnish, Greek, Italian, Norwegian, Dutch, Portuguese, Russian, Swedish).</li> <li>• <b>Update:</b> Internet connection required, update via AppStore.</li> </ul>	1
<b>Kit:</b> No. <b>Labelling:</b> See appendix.			
2.7	<b>Device and accessories composition:</b> <ul style="list-style-type: none"> <li>• Camera materials : Housing: machined aluminum (6061 T6) Window: Black polyoxymethylene (POM) Standby button and triple button: liquid silicone ( LSR 2650 black)</li> </ul>		

	<p>Latex free. DEHP free. Halogen free. No products of animal or biological origin.</p>
2.8	<p><b>Application:</b> Colposcopy examinations. <b>Intended use:</b> The device is indicated for use by a healthcare professional in a procedure involving a colposcope, such as the visualization of tissues of the vulva, vagina, cervix and anogenital region, in a healthcare center equipped with an appropriate configuration.</p>

### 3. Sterilization process

	<p><b>Medical device supplied sterile :</b> No. <b>Device sterilization mode:</b> Non-sterilizable. <b>Is this medical device indicated/used in neonates :</b> No. <b>Is this medical device indicated/used in premature newborns :</b> No. <b>Is this medical device indicated/used in infants :</b> No.</p>
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### 4. Storage conditions

	<p><b>Storage conditions:</b> 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. <b>Expiry date :</b> Non-sterile devices can be stored for any length of time.</p>
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### 5. Safety in use

5.1	<b>Technical safety :</b> Follow the operating instructions.
5.2	<b>Biological safety:</b> N/A

### 6. Directions for use

6.1	<b>Instructions for use :</b> Follow the operating instructions.
6.2	<b>Indications :</b> to refer to 2.9.
6.3	<b>Precautions for use :</b> Follow the operating instructions.
6.4	<b>Contraindications</b> Follow the instructions.

### 7. Additional product information

	N/A
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### 8. List of appendices

	<ul style="list-style-type: none"> <li>- Labelling and traceability label</li> <li>- Leaflet(D900 700 111)</li> <li>- User manual (D900 700 172/ D900 700 052)</li> <li>- CE certificate</li> </ul>
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## 9. Photos

a.



b.

b.1



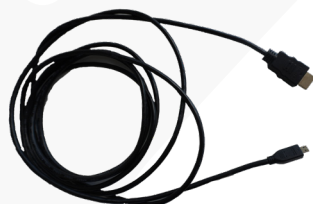
b.2



b.3



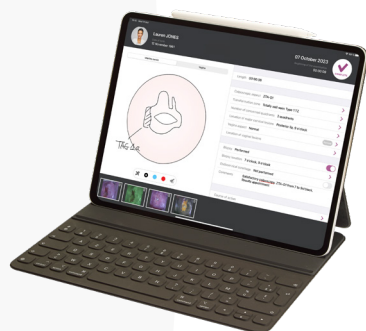
b.4



b.5



c.



d.



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