

## EC Declaration of Conformity

According to Annex II Directive 93/42/EEC concerning medical devices amended by the Directive 2007/47/EC

Manufacturer name: Delmont imaging,  
Manufacturer address: 390 avenue du Mistral, 13600 La Ciotat, France  
Manufacturer SRN: FR-MF-000000157

Declare under our sole responsibility (see list below for details and accessories) the medical device:

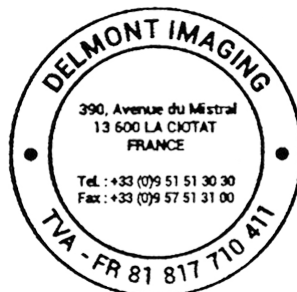
Generic name: Resectoscopy system  
Risk classification: IIb, rule 9  
Basic UDI-DI: 37012178RESSLA

Based on the following elements:

Conformity route: Annex II point 3 Directive 93/42/CEE  
Technical file: TF- RESS  
Notified body: SIQ (1304), Mašera-Spasićeva ulica 10, SI-1000 Ljubljana, Slovenia  
EC certificate: MDD-085

We, the undersigned, certify and declare that the medical device is in conformity with the relevant essential requirements set out in Annex I to Directive 93/42/EEC.

Representative name: MONTILLOT Pierre  
Representative function: CEO  
Revision date: 2024-08-22



#### Applicable standards

EN 556-1:2002; EN 60601-1:2006/A1:2014/A12:2016/A2:2021; EN 60601-1-6:2010/A1:2015/A2:2021; EN 60601-2-2:2018; EN 62366-1:2015/A1:2020; EN ISO 10993-1:2020; EN ISO 10993-10:2013; EN ISO 10993-12:2021; EN ISO 10993-18:2020; EN ISO 10993-5:2010; EN ISO 10993-7:2008/A1:2022; EN ISO 11135-1:2014/A1:2019; EN ISO 11138-2:2017; EN ISO 11607-1:2020; EN ISO 11607-2:2020; EN ISO 11737-2:2020; EN ISO 13485:2016/A11:2021; EN ISO 14971:2019; EN ISO 15223-1:2021; EN ISO 17664-1:2021; EN ISO 17665-1:2006; EN ISO 20417:2021; EN ISO 7153-1:2016; EN ISO 80369-1:2018;

| REF          | GTIN/UDI-DI    | Description EN                                                                                             |
|--------------|----------------|------------------------------------------------------------------------------------------------------------|
| D300 130 000 | 03701217801271 | Outer sheath, double flow, 18,5Fr. resectoscope                                                            |
| D300 130 001 | 03701217801288 | Inner sheath, rotatable, 18,5Fr. resectoscope                                                              |
| D300 130 002 | 03701217801295 | Passive working element for 18,5Fr. resectoscope                                                           |
| D300 130 003 | 03701217801301 | Standard obturator for 18,5Fr. resectoscope                                                                |
| D300 130 004 | 03701217801318 | Outer sheath, double flow, 26Fr. resectoscope                                                              |
| D300 130 005 | 03701217801325 | Inner sheath, rotatable, 26Fr. resectoscope                                                                |
| D300 130 006 | 03701217801332 | Passive working element for 26Fr. resectoscope                                                             |
| D300 130 007 | 03701217801349 | Standard obturator for inner sheath of 26Fr. resectoscope                                                  |
| D300 130 008 | 03701217801356 | Active working element for 26Fr. resectoscope                                                              |
| D300 130 009 | 03701217801363 | Active working element for 18,5Fr. resectoscope                                                            |
| D300 130 010 | 03701217801370 | Visual obturator for 26Fr. resectoscope                                                                    |
| D300 130 046 | 03701217801738 | Examination bridge for 26Fr. resectoscope, with 6Fr. Operative canal - for 4mm 12° or 30° hysteroscope     |
| D300 130 063 | 03701217801905 | Quick-lock adapter for Ellik evacuator connection. Compatible with MaxiCare & ReseCare.                    |
| D300 130 085 | 03701217802124 | Examination bridge for 18,5Fr. resectoscope, with 5Fr. Operative canal - for 2,9mm 12° or 30° hysteroscope |
| D300 130 088 | 03701217806481 | Outer sheath, double flow, 18,5Fr. bariatric resectoscope                                                  |
| D300 130 089 | 03701217806498 | Inner sheath, rotatable, 18,5Fr. bariatric resectoscope                                                    |
| D300 130 091 | 03701217806511 | Standard obturator for 18,5Fr. bariatric resectoscope                                                      |
| D300 130 093 | 03701217806856 | Standard obturator for 26Fr. resectoscope outer sheath                                                     |
| D300 130 094 | 03701217806863 | Standard obturator for inner sheath of 18,5Fr. resectoscope                                                |
| D300 140 000 | 03701217802131 | Cutting loop 30°, 18,5Fr. resectoscope                                                                     |
| D300 140 001 | 03701217802148 | Cutting loop, straight, 18,5Fr. resectoscope                                                               |
| D300 140 002 | 03701217802155 | Knife electrode, 18,5Fr. resectoscope                                                                      |
| D300 140 003 | 03701217802162 | Coagulating rollerball electrode, 18,5Fr. resectoscope                                                     |
| D300 140 004 | 03701217802179 | Cutting loop 30°, 26Fr. resectoscope                                                                       |
| D300 140 005 | 03701217802186 | Knife electrode, 26Fr. resectoscope                                                                        |
| D300 140 006 | 03701217802193 | Coagulating electrode rollerball, 26Fr. resectoscope                                                       |
| D300 140 007 | 03701217802209 | Cutting loop, straight, 26Fr. resectoscope.                                                                |

| REF          | GTIN/UDI-DI    | Description EN                                                                        |
|--------------|----------------|---------------------------------------------------------------------------------------|
| D300 140 008 | 03701217802216 | Vaporization electrode, rollerball with tip, 26Fr. resectoscope                       |
| D300 140 009 | 03701217802223 | Vaporization electrode rollerball smooth, 26Fr. resectoscope                          |
| D300 140 019 | 03701217802322 | Coagulating electrode ball, bipolar, 26Fr. resectoscope                               |
| D300 140 026 | 03701217802391 | Cutting loop 0°, bipolar, 26Fr. resectoscope                                          |
| D300 140 067 | 03701217802766 | STERILE. Cutting loop 30°, 18,5Fr. resectoscope. Single use                           |
| D300 140 068 | 03701217802773 | STERILE. Cutting loop, straight, 18,5Fr. resectoscope. Single use                     |
| D300 140 069 | 03701217802780 | STERILE. Knife electrode, 18,5Fr. resectoscope. Single use                            |
| D300 140 070 | 03701217802797 | STERILE. Coagulating rollerball electrode, 18,5Fr. resectoscope. Single use           |
| D300 140 078 | 03701217802940 | STERILE. Cutting loop 30°, 26Fr. resectoscope. Single use                             |
| D300 140 079 | 03701217802957 | STERILE. Knife electrode, 26Fr. resectoscope. Single use                              |
| D300 140 080 | 03701217802964 | STERILE. Coagulating rollerball electrode, 26Fr. resectoscope. Single use             |
| D300 140 081 | 03701217802971 | STERILE. Cutting loop, straight, 26Fr. resectoscope. Single use                       |
| D300 140 082 | 03701217802988 | STERILE. Vaporization electrode rollerball with tip, 26Fr. resectoscope. Single use   |
| D300 140 083 | 03701217802995 | STERILE. Vaporization electrode rollerball smooth, 26Fr. resectoscope. Single use     |
| D300 140 086 | 03701217806542 | Cutting loop 30°, 18,5Fr. bariatric resectoscope                                      |
| D300 140 087 | 03701217806559 | Cutting loop, straight, 18,5Fr. bariatric resectoscope                                |
| D300 140 088 | 03701217806566 | Knife electrode, 18,5Fr. bariatric resectoscope                                       |
| D300 140 089 | 03701217806573 | Coagulating rollerball electrode, 18,5Fr. bariatric resectoscope                      |
| D300 140 090 | 03701217807068 | Vaporisation electrode, rollerball with tip, 18,5Fr. resectoscope                     |
| D300 140 091 | 03701217807051 | STERILE. Vaporisation electrode rollerball with tip, 18,5Fr. resectoscope. Single use |
| D300 140 092 | 03701217807044 | Vaporization electrode flat cone, bipolar, 26Fr. resectoscope                         |
| D300 140 093 | 03701217807037 | Vaporization electrode hollow cone, bipolar, 26Fr. resectoscope                       |
| D300 140 094 | 03701217807020 | Vaporization electrode mushroom, bipolar, 26Fr. resectoscope                          |
| D300 140 095 | 03701217807013 | Vaporization electrode striated mushroom, bipolar, 26Fr. resectoscope                 |
| D300 140 122 | 03701217803688 | Vaporisation electrode, rollerball with tip, 18,5Fr. bariatric resectoscope           |
| D300 190 001 | 03701217807839 | Working element stopper for resectoscopes                                             |