

CE declaration of conformity – Directive 93/42/EEC  
**Class IIa products**

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We

**MAILLEFER INSTRUMENTS HOLDING Sàrl and its subsidiaries**

(including the subsidiaries: Maillefer Instruments Trading sàrl, Maillefer Instruments Manufacturing sàrl, Maillefer Instruments Consulting sàrl)  
Trading as Dentsply Maillefer

**Chemin du Verger 3, CH-1338 Ballaigues / Switzerland**

declare on our own responsibility that the following medical devices listed in enclosure F 711.208.E: **Reference List A41** (8 pages), version n°05.

Conform to the requirements of Council Directive 93/42/EEC and meet the Essential Requirements of Annex I. All devices are designed, manufactured, tested and released for sale in accordance with the technical documentation.

This declaration is based on the following data:

- ✚ Technical documentation demonstrating the product conformity to the requirements of the directive.
- ✚ The CE certificate n° **16708** of acceptance of the complete assurance system according to annex II **point 3**, of the directive 93/42/EEC.
- ✚ Applied norms: Listed in **F711.208.E Reference List A41**
- ✚ Notified body: G-MED-LNE, F-75724 Paris Cedex 15
- ✚ Conformity assessment procedure: Annex II **point 3**, of the directive 93/42/EEC

Dentsply Maillefer's Division maintains a quality management system that complies with the United States Food and Drug Administration 21 CFR Part 820, EN ISO 13485:2012, the European Union Council Directive 93/42/EEC, the Japanese PAL law.

Ballaigues, 28th March 2014

Management Representative



Luc ETIENNE

MAILLEFER INSTRUMENTS  
HOLDING Sàrl

Encl.





## Reference list

### A41: OBL Family - 1

Edition : 05

Date: 18.03.2014

Signature :



Code: D: Displacement from other list / N : New reference / M : Modification / R : Removed  
 GMDN : Global Medical Device Nomenclature  
 REF : Maillefer reference number  
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| Code | REF   | Proprietary Name                           | Intended use   | GMDN # | GMDN definition                             | Rule         | Class | S/M | Standards  |
|------|-------|--|--|--------|---|--------------|-------|-----|--|
| D    | A022C | Gutta-Percha-Points                        | These points are used to fill the root canals.                                 | 31872  | Dental material, root filling, gutta-percha | 8-1st hyphen | Ila   | -   | EN ISO 13485, ISO 14971, EN 1641, ISO 6877, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664 |
| D    | A022E | Gutta-Percha-Points                        | These points are used to fill the root canals.                                 | 31872  | Dental material, root filling, gutta-percha | 8-1st hyphen | Ila   | -   | EN ISO 13485, ISO 14971, EN 1641, ISO 6877, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664 |
| D    | A022F | Auxiliary Gutta-Percha-Points              | These points are used to fill the root canals.                                 | 31872  | Dental material, root filling, gutta-percha | 8-1st hyphen | Ila   | -   | EN ISO 13485, ISO 14971, EN 1641, ISO 6877, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664 |
| D    | A022G | Gutta-Percha-Points ISO Color-Coded        | These points are used to fill the root canals.                                 | 31872  | Dental material, root filling, gutta-percha | 8-1st hyphen | Ila   | -   | EN ISO 13485, ISO 14971, EN 1641, ISO 6877, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664 |
| D    | A022J | Absorbent Paper points ISO Color-Coded .04 | To dry the root canal used with the Profile system .04.                        | 38777  | Absorbent point, dental                     | 6            | Ila   | -   | EN ISO 13485, ISO 14971, EN 1641, ISO 7551, ISO 15223, EN 1041, ISO 10993-1              |
| D    | A022K | Absorbent Paper points ISO Color-Coded .06 | To dry the root canal used with the Profile system .06.                        | 38777  | Absorbent point, dental                     | 6            | Ila   | -   | EN ISO 13485, ISO 14971, EN 1641, ISO 7551, EN 980, ISO 15223, EN 1041, ISO 10993-1      |
| D    | A022L | Auxiliary Gutta-Percha-Points              | These points are used to fill the root canals.                                 | 31872  | Dental material, root filling, gutta-percha | 8-1st hyphen | Ila   | -   | EN ISO 13485, ISO 14971, EN 1641, ISO 6877, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664 |
| D    | A022M | Gutta-Percha-Points ISO Color-Coded .04    | These points are used to fill the root canals used with the Profile system.04. | 31872  | Dental material, root filling, gutta-percha | 8-1st hyphen | Ila   | -   | EN ISO 13485, ISO 14971, EN 1641, ISO 6877, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664 |
| D    | A022N | Gutta-Percha-Points ISO Color-Coded .06    | These points are used to fill the root canals used with the Profile system.06. | 31872  | Dental material, root filling, gutta-percha | 8-1st hyphen | Ila   | -   | EN ISO 13485, ISO 14971, EN 1641, ISO 6877, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664 |

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|------|-------|--|---|--------|---|--------------|-------|-----|--|
| D    | A0220 | ProTaper Next Gutta-Percha Points          | These points are used to fill the root canals during treatment with ProTaper Next system. | 31872  | Dental material, root filling, gutta-percha | 8-1st hyphen | Ila   | -   | EN ISO 13485, ISO 14971, EN 1641, ISO 6877, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664 |
|      | A022Q | ProTaper Next Paper Points                 | To dry the root canal.  | 38777  | Absorbent point, dental                     | 6            | Ila   | S   | EN ISO 13485, ISO 14971, EN 1641, ISO 7551, ISO 15223, EN 1041, ISO 10993-1              |
| D    | A022R | Absorbent Paper points ISO Color-Coded     | To dry the root canal.  | 38777  | Absorbent point, dental                     | 6            | Ila   | -   | EN ISO 13485, ISO 14971, EN 1641, ISO 7551, ISO 15223, EN 1041, ISO 10993-1              |
| D    | A022T | Absorbent Paper Points .02 ISO Color-Coded | To dry the root canal.  | 38777  | Absorbent point, dental                     | 6            | Ila   | S   | EN ISO 13485, ISO 14971, EN 1641, ISO 7551, ISO 15223, EN 1041, ISO 10993-1              |
| D    | A022W | Paper points for ProTaper Universal        | To dry the root canal.  | 38777  | Absorbent point, dental                     | 6            | Ila   | S   | EN ISO 13485, ISO 14971, EN 1641, ISO 7551, ISO 15223, EN 1041, ISO 10993-1              |
| D    | A022X | Gutta-Percha Points for ProTaper Universal | These points are used to fill the root canals used with the ProTaper system.              | 31872  | Dental material, root filling, gutta-percha | 8-1st hyphen | Ila   | -   | EN ISO 13485, ISO 14971, EN 1641, ISO 6877, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664 |
| R    | A022Y | Gutta-Percha for GT                        | These points are used to fill the root canals used with the GT system.                    | 31872  | Dental material, root filling, gutta-percha | 8-1st hyphen | Ila   | -   | EN ISO 13485, ISO 14971, EN 1641, ISO 6877, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664 |
| R    | A022Z | Paper points for system GT                 | To dry the root canal used with the system GT.  | 38777  | Absorbent point, dental                     | 6            | Ila   | -   | EN ISO 13485, ISO 14971, EN 1641, ISO 7551, ISO 15223, EN 1041, ISO 10993-1              |
| D    | A023Y | GT series X Gutta-Percha-Points            | These points are used to fill the root canals used with the GT series X system.           | 31872  | Dental material, root filling, gutta-percha | 8-1st hyphen | Ila   | -   | EN ISO 13485, ISO 14971, EN 1641, ISO 6877, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664 |

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|------|-------|---|--|--------|---|--------------|-------|-----|---|
| D    | A023Z | GT series X Paper Points                    | To dry the root canal used with the system GT series X.  | 38777  | Absorbent point, dental                     | 6            | Ila   | -   | EN ISO 13485, ISO 14971, EN 1641, ISO 7551, ISO 15223, EN 1041, ISO 10993-1   |
| D    | A024W | Paper points for WaveOne                    | To dry the root canal during treatment with wave one system.   | 38777  | Absorbent point, dental                     | 6            | Ila   | S   | EN ISO 13485, ISO 14971, EN 1641, ISO 7551, ISO 15223, EN 1041, ISO 10993-1   |
| D    | A024X | WaveOne Gutta-Percha points                 | These points are used to fill the root canals during treatment with Wave one system.   | 31872  | Dental material, root filling, gutta-percha | 8-1st hyphen | Ila   | -   | EN ISO 13485, ISO 14971, EN 1641, ISO 6877, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664                                    |
|      | A0166 | Thermafil Obturators                        | These points are destined for root canal obturation.   | 31872  | Dental material, root filling, gutta-percha | 8-1st hyphen | Ila   | -   | EN ISO 13485, ISO 14971, EN 1641, ISO 6877 (part.), ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664                            |
|      | A0167 | Thermafil obturators assorted posterior kit | These points are destined for root canal obturation.   | 31872  | Dental material, root filling, gutta-percha | 8-1st hyphen | Ila   | -   | EN ISO 13485, ISO 14971, EN 1641, ISO 6877 (part.), ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664                            |
|      | A0168 | Thermafil obturators assorted anterior kit  | These points are destined for root canal obturation.   | 31872  | Dental material, root filling, gutta-percha | 8-1st hyphen | Ila   | -   | EN ISO 13485, ISO 14971, EN 1641, ISO 6877 (part.), ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664                            |
|      | A0348 | Thermafil Obturators                        | The points are used to fill the root canals. The Ref. A0348 is identical to the Ref. A0166, but it is packed per 30 pieces in place of 6 pieces. | 31872  | Dental material, root filling, gutta-percha | 8-1st hyphen | Ila   | -   | EN ISO 13485, ISO 14971, EN 1641, ISO 6877 (part.), ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664                            |
| R    | A0378 | GT Hand Files                               | For manual preparation of the root canal.  | 31878  | File, endodontic, hand-held                 | 6-2nd hyphen | I     | -   | EN ISO 13485, ISO 14971, EN 1639, ISO 3630-1, ISO 10993-1, ISO 17664, ISO 17665-1, ISO 15223-1, EN 1041                     |
| R    | A0420 | System GT Rotary Files                      | Engine driven instrument for root canal shaping.   | 40529  | Rasp, endodontic, powered                   | 6            | Ila   | -   | EN ISO 13485, ISO 14971, EN 1639, ISO 1797-1, ISO 3630-1 (part.), ISO 10993-1, ISO 17664, ISO 17665-1, ISO 15223-1, EN 1041 |

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|------|-------|--------------------------------|--|--------|---|--------------|-------|-----|---|
| R    | A0421 | GT Obturators                  | These points are destined for root canal obturation. | 31872  | Dental material, root filling, gutta-percha | 8-1st hyphen | Ila   | -   | EN ISO 13485, ISO 14971, EN 1641, ISO 6877 (part.), ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664                            |
| R    | A0430 | System GT Rotary Files         | Engine driven instrument for root canal shaping.     | 40529  | Rasp, endodontic, powered                   | 6            | Ila   | -   | EN ISO 13485, ISO 14971, EN 1639, ISO 1797-1, ISO 3630-1 (part.), ISO 10993-1, ISO 17664, ISO 17665-1, ISO 15223-1, EN 1041 |
| R    | A0431 | GT Obturators                  | These points are destined for root canal obturation. | 31872  | Dental material, root filling, gutta-percha | 8-1st hyphen | Ila   | -   | EN ISO 13485, ISO 14971, EN 1641, ISO 6877 (part.), ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664                            |
|      | A0435 | System GT Accessory Files      | Engine driven instrument for root canal shaping.     | 40529  | Rasp, endodontic, powered                   | 6            | Ila   | -   | EN ISO 13485, ISO 14971, EN 1639, ISO 1797-1, ISO 3630-1 (part.), ISO 10993-1, ISO 17664, ISO 17665-1, ISO 15223-1, EN 1041 |
| R    | A0436 | System GT Obturators Accessory | These points are destined for root canal obturation. | 31872  | Dental material, root filling, gutta-percha | 8-1st hyphen | Ila   | -   | EN ISO 13485, ISO 14971, EN 1641, ISO 6877 (part.), ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664                            |
| R    | A0440 | System GT Rotary Files         | Engine driven instrument for root canal shaping.     | 40529  | Rasp, endodontic, powered                   | 6            | Ila   | -   | EN ISO 13485, ISO 14971, EN 1639, ISO 1797-1, ISO 3630-1 (part.), ISO 10993-1, ISO 17664, ISO 17665-1, ISO 15223-1, EN 1041 |
| R    | A0441 | GT Obturators                  | These points are destined for root canal obturation. | 31872  | Dental material, root filling, gutta-percha | 8-1st hyphen | Ila   | -   | EN ISO 13485, ISO 14971, EN 1641, ISO 6877 (part.), ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664                            |
|      | A0450 | System GT Accessory Files      | Engine driven instrument for root canal shaping.     | 40529  | Rasp, endodontic, powered                   | 6            | Ila   | -   | EN ISO 13485, ISO 14971, EN 1639, ISO 1797-1, ISO 3630-1 (part.), ISO 10993-1, ISO 17664, ISO 17665-1, ISO 15223-1, EN 1041 |
|      | A0451 | System GT Obturators Accessory | These points are destined for root canal obturation. | 31872  | Dental material, root filling, gutta-percha | 8-1st hyphen | Ila   | -   | EN ISO 13485, ISO 14971, EN 1641, ISO 6877 (part.), ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664                            |

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|------|-------|--------------------------------|--|--------|---|--------------|-------|-----|---|
|      | A0470 | System GT Accessory Files      | Engine driven instrument for root canal shaping.     | 40529  | Rasp, endodontic, powered                   | 6            | Ila   | -   | EN ISO 13485, ISO 14971, EN 1639, ISO 1797-1, ISO 3630-1 (part.), ISO 10993-1, ISO 17664, ISO 17665-1, ISO 15223-1, EN 1041 |
| R    | A0471 | System GT Obturators Accessory | These points are destined for root canal obturation. | 31872  | Dental material, root filling, gutta-percha | 8-1st hyphen | Ila   | -   | EN ISO 13485, ISO 14971, EN 1641, ISO 6877 (part.), ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664                            |
| R    | A0480 | System GT Rotary Files         | Set for mechanical preparation of the root canal.    | 38442  | Unclassified                                | 6            | Ila   | -   | EN ISO 13485, ISO 14971, EN 1639, ISO 1797-1, ISO 3630-1 (part.), ISO 10993-1, ISO 17664, ISO 17665-1, ISO 15223-1, EN 1041 |
| R    | A0481 | GT Obturators                  | These points are destined for root canal obturation. | 31872  | Dental material, root filling, gutta-percha | 8-1st hyphen | Ila   | -   | EN ISO 13485, ISO 14971, EN 1641, ISO 6877 (part.), ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664                            |
|      | A0485 | System GT Accessory Files      | Engine driven instrument for root canal shaping.     | 40529  | Rasp, endodontic, powered                   | 6            | Ila   | -   | EN ISO 13485, ISO 14971, EN 1639, ISO 1797-1, ISO 3630-1 (part.), ISO 10993-1, ISO 17664, ISO 17665-1, ISO 15223-1, EN 1041 |
|      | A0486 | System GT Obturators Accessory | These points are destined for root canal obturation. | 31872  | Dental material, root filling, gutta-percha | 8-1st hyphen | Ila   | -   | EN ISO 13485, ISO 14971, EN 1641, ISO 6877 (part.), ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664                            |
|      | A0521 | GT Series X Obturator          | These points are destined for root canal obturation. | 31872  | Dental material, root filling, gutta-percha | 8-1st hyphen | Ila   | -   | EN ISO 13485, ISO 14971, EN 1641, ISO 6877 (part.), ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664                            |
|      | A0531 | GT Series X Obturator          | These points are destined for root canal obturation. | 31872  | Dental material, root filling, gutta-percha | 8-1st hyphen | Ila   | -   | EN ISO 13485, ISO 14971, EN 1641, ISO 6877 (part.), ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664                            |
|      | A0541 | GT Series X Obturator          | These points are destined for root canal obturation. | 31872  | Dental material, root filling, gutta-percha | 8-1st hyphen | Ila   | -   | EN ISO 13485, ISO 14971, EN 1641, ISO 6877 (part.), ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664                            |

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|------|-------|--------------------------------|--|--------|-----------------------------|------|-------|-----|--|
|      | A0620 | ProUltra                       | Insert for use on handpieces driven by an ultrasonic generator.  | 38442  | Unclassified                | 6    | Ila   | -   | EN ISO 13485, ISO 14971, EN 1639, ISO 22374, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664, ISO 17665-1 |
|      | A0621 | ProUltra                       | Insert for use on handpieces driven by an ultrasonic generator.  | 38442  | Unclassified                | 6    | Ila   | -   | EN ISO 13485, ISO 14971, EN 1639, ISO 22374, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664, ISO 17665-1 |
|      | A0630 | ProUltra                       | Insert for use on handpieces driven by an ultrasonic generator.  | 38442  | Unclassified                | 6    | Ila   | -   | EN ISO 13485, ISO 14971, EN 1639, ISO 22374, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664, ISO 17665-1 |
|      | A0631 | ProUltra                       | Insert for use on handpieces driven by an ultrasonic generator.  | 38442  | Unclassified                | 6    | Ila   | -   | EN ISO 13485, ISO 14971, EN 1639, ISO 22374, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664, ISO 17665-1 |
|      | A0640 | ProUltra                       | Insert for use on handpieces driven by an ultrasonic generator.  | 38442  | Unclassified                | 6    | Ila   | -   | EN ISO 13485, ISO 14971, EN 1639, ISO 22374, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664, ISO 17665-1 |
|      | A0650 | ProUltra                       | Insert for use on handpieces driven by an ultrasonic generator.  | 38442  | Unclassified                | 6    | Ila   | -   | EN ISO 13485, ISO 14971, EN 1639, ISO 22374, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664, ISO 17665-1 |
|      | A0901 | GLYDE® File Prep syringe kit   | Lubricate removing debris with hypochlorite (syringes).          | 35970  | Syringe, dental, irrigating | 9    | Ila   | -   | EN ISO 13485, ISO 14971, EN 1640, ISO 10993, ISO 15223-1, EN 1041                                      |
|      | A0902 | GLYDE® File Prep Intro Package | Lubricate removing debris with hypochlorite (syringes and tips). | 35970  | Syringe, dental, irrigating | 9    | Ila   | -   | EN ISO 13485, ISO 14971, EN 1640, ISO 10993, ISO 15223-1, EN 1041                                      |
|      | A0903 | GLYDE® File Prep Syringe Tips  | Tips.  | 35210  | Needle, blunt, single use   | 9    | Ila   | -   | EN ISO 13485, ISO 14971, EN 1640, ISO 10993, ISO 15223-1, EN 1041                                      |

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|------|---------|--|--|--------|---|------|-------|-----|--|
|      | A0904   | GLYDE® File Prep Sample Pack                       | Lubricate removing debris with hypochlorite (syringes and tips).           | 35970  | Syringe, dental, irrigating                   | 9    | Ila   | -   | EN ISO 13485, ISO 14971, EN 1640, ISO 10993, ISO 15223-1, EN 1041  |
|      | A0905   | GLYDE® doses pack                                  | Lubricate removing debris with hypochlorite (syringes and tips).           | 35970  | Syringe, dental, irrigating                   | 9    | Ila   | -   | EN ISO 13485, ISO 14971, EN 1640, ISO 10993, ISO 15223-1, EN 1041  |
| R    | A0906   | DIMS IV  | Solvent of root canal filling materials from Eugenol                       | 38442  | Unclassified                                  | 7    | Ila   | -   | EN ISO 13485, ISO 14971, EN 1641, EN 1041, ISO 10993, ISO 15223-1, ISO 8601  |
|      | A1032   | X-SMART® Plus                                      | Endodontic micromotor to drive endodontic instruments.                     | 38347  | Drill, dental, electrically powered handpiece | 9    | Ila   | -   | EN ISO 13485, ISO 14971, EN 1640, EN 60601-1, EN 60601-1-2, EN 60601-1-4, EN 60601-1-6, EN 62304, EN 62366, , ISO 11498, ISO 15223-1, ISO 17664, ISO 17665-1, EN 1041, ISO 10993-1 |
|      | A1032-1 | X-SMART® Plus Grant Program                        | Endodontic micromotor to drive endodontic instruments.                     | 38347  | Drill, dental, electrically powered handpiece | 9    | Ila   | -   | EN ISO 13485, ISO 14971, EN 1640, EN 60601-1, EN 60601-1-2, EN 60601-1-4, EN 60601-1-6, EN 62304, EN 62366, , ISO 11498, ISO 15223-1, ISO 17664, ISO 17665-1, EN 1041, ISO 10993-1 |
|      | A1032-2 | X-SMART® Plus Demo Case                            | Demo case intended for the use of Salesmen.                                | 38347  | Drill, dental, electrically powered handpiece | 9    | Ila   | -   | EN ISO 13485, ISO 14971, EN 1640, EN 60601-1, EN 60601-1-2, EN 60601-1-4, EN 60601-1-6, EN 62304, EN 62366, , ISO 11498, ISO 15223-1, ISO 17664, ISO 17665-1, EN 1041, ISO 10993-1 |
|      | A1032-3 | X-SMART® Plus, PROPEX® II, Thermanprep 2 Demo case | Demo case intended for the use of Salesmen.                                | 38347  | Drill, dental, electrically powered handpiece | 9    | Ila   | -   | EN ISO 13485, ISO 14971, EN 1640, EN 60601-1, EN 60601-1-2, EN 60601-1-4, EN 60601-1-6, EN 62304, EN 62366, , ISO 11498, ISO 15223-1, ISO 17664, ISO 17665-1, EN 1041, ISO 10993-1 |
|      | A1033   | X-SMART® Plus 6:1 Contra-angle                     | Contra-angle linked to a micromotor in which dental instruments are fitted | 31823  | Drill, dental, attachment                     | 9    | Ila   | -   | EN ISO 13485, ISO 14971, EN 1640, EN 60601-1, EN 60601-1-2, EN 60601-1-4, EN 60601-1-6, EN 62304, EN 62366, , ISO 11498, ISO 15223-1, ISO 17664, ISO 17665-1, EN 1041, ISO 10993-1 |
|      | A1034-3 | X-SMART® Plus Motor Handpiece                      | Endodontic micromotor to drive endodontic instruments.                     | 38347  | Drill, dental, electrically powered handpiece | 9    | Ila   | -   | EN ISO 13485, ISO 14971, EN 1640, EN 60601-1, EN 60601-1-2, EN 60601-1-4, EN 60601-1-6, EN 62304, EN 62366, , ISO 11498, ISO 15223-1, ISO 17664, ISO 17665-1, EN 1041, ISO 10993-1 |

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| Code | REF   | Proprietary Name                   | Intended use   | GMDN # | GMDN definition                             | Rule         | Class | S/M | Standards  |
|------|-------|------------------------------------|--|--------|---|--------------|-------|-----|--|
|      | A1411 | Protaper Universal obturator F1-F5 | These points are destined for root canal obturation.                 | 31872  | Dental material, root filling, gutta-percha | 8-1st hyphen | Ila   | -   | EN ISO 13485, ISO 14971, EN 1641, ISO 6877 (part.), ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664 |
|      | A1700 | WAVEONE® obturators                | Used to obture the root canal after treatment using Wave one system. | 31872  | Dental material, root filling, gutta-percha | 8-1st hyphen | Ila   | -   | EN ISO 13485, ISO 14971, EN 1641, ISO 6877 (part.), ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664 |