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| Company: | Medacta International SA |
| Address: | Strada Regina - 6874 - Castel San Pietro - CH |
| Contacts : | Tel: +41 91 696 60 60; Fax: +41 91 696 60 66 |
| Model: | MectaCer IMPLANTS _ TF AI-CE-01 |
| Notified Body: | Kiwa Cermet Italia S.p.A Via Cadriano, 23 - 40057 Granarolo dell'Emilia (BO) tel. + 39 051 - 4593111 |

Medical devices directory codes:

| Ref. No. | Description |
|-----------------|---|
| 01.29.301 | Ceramic Liner Ø 28 / C |
| 01.29.302 | Ceramic Liner Ø 28 / D |
| 01.29.303 | Ceramic Liner Ø 28 / E |
| 01.29.304 | Ceramic Liner Ø 28 / F |
| 01.29.305 | Ceramic Liner Ø 28 / G |
| 01.29.306 | Ceramic Liner Ø 32 / D |
| 01.29.307 | Ceramic Liner Ø 32 / E |
| 01.29.308 | Ceramic Liner Ø 32 / F |
| 01.29.309 | Ceramic Liner Ø 32 / G |
| 01.29.310 | Ceramic Liner Ø 36 / E |
| 01.29.311 | Ceramic Liner Ø 36 / F |
| 01.29.312 | Ceramic Liner Ø 36 / G |
| 01.29.401 | Ceramic Liner Ø 28 / A |
| 01.29.402 | Ceramic Liner Ø 28 / B |
| 01.29.403 | Ceramic Liner Ø 28 / C |
| 01.29.404 | Ceramic Liner Ø 28 / D |
| 01.29.405 | Ceramic Liner Ø 28 / E |
| 01.29.406 | Ceramic Liner Ø 28 / F |
| 01.29.407 | Ceramic Liner Ø 28 / G |
| 01.29.408 | Ceramic Liner Ø 32 / C |
| 01.29.409 | Ceramic Liner Ø 32 / D |
| 01.29.410 | Ceramic Liner Ø 32 / E |
| 01.29.411 | Ceramic Liner Ø 32 / F |
| 01.29.412 | Ceramic Liner Ø 32 / G |
| 01.29.413 | Ceramic Liner Ø 36 / E |
| 01.29.414 | Ceramic Liner Ø 36 / F |
| 01.29.415 | Ceramic Liner Ø 36 / G |
| 01.29.416 | Ceramic Liner Ø 40 / F |
| 01.29.417 | Ceramic Liner Ø 40 / G |
| 01.29.120 | Ceramic Ball Head 10/12 ø 28 Size S -3.5 |
| 01.29.121 | Ceramic Ball Head 10/12 ø 28 Size M 0 |
| 01.29.122 | Ceramic Ball Head 10/12 ø 28 Size L +3.5 |
| 01.29.123 | Ceramic Ball Head 10/12 ø 32 Size S -4 |
| 01.29.124 | Ceramic Ball Head 10/12 ø 32 Size M 0 |
| 01.29.125 | Ceramic Ball Head 10/12 ø 32 Size L +4 |
| 01.29.100 | Ceramic Ball Head 12/14 ø 28 Size S -3.5 |
| 01.29.101 | Ceramic Ball Head 12/14 ø 28 Size M 0 |
| 01.29.102 | Ceramic Ball Head 12/14 ø 28 Size L +3.5 |
| 01.29.103 | Ceramic Ball Head 12/14 ø 32 Size S -4 |
| 01.29.104 | Ceramic Ball Head 12/14 ø 32 Size M 0 |
| 01.29.105 | Ceramic Ball Head 12/14 ø 32 Size L +4 |
| 01.29.106 | Ceramic Ball Head 12/14 ø 36 Size S -4 |
| 01.29.107 | Ceramic Ball Head 12/14 ø 36 Size M 0 |
| 01.29.108 | Ceramic Ball Head 12/14 ø 36 Size L +4 |
| 01.29.201 | BIOLOX Delta Ceramic Ball Head 12/14 ø 28 Size S -3.5 |
| 01.29.202 | BIOLOX Delta Ceramic Ball Head 12/14 ø 28 Size M 0 |
| 01.29.203 | BIOLOX Delta Ceramic Ball Head 12/14 ø 28 Size L +3.5 |
| 01.29.204 | BIOLOX Delta Ceramic Ball Head 12/14 ø 32 Size S -4 |
| 01.29.205 | BIOLOX Delta Ceramic Ball Head 12/14 ø 32 Size M 0 |
| 01.29.206 | BIOLOX Delta Ceramic Ball Head 12/14 ø 32 Size L +4 |
| 01.29.207 | BIOLOX Delta Ceramic Ball Head 12/14 ø 32 Size XL +7 |
| 01.29.208 | BIOLOX Delta Ceramic Ball Head 12/14 ø 36 Size S -4 |
| 01.29.209 | BIOLOX Delta Ceramic Ball Head 12/14 ø 36 Size M 0 |
| 01.29.210 | BIOLOX Delta Ceramic Ball Head 12/14 ø 36 Size L +4 |
| 01.29.211 | BIOLOX Delta Ceramic Ball Head 12/14 ø 36 Size XL +8 |
| 01.29.212 | BIOLOX Delta Ceramic Ball Head 12/14 ø 40 Size S -4 |
| 01.29.213 | BIOLOX Delta Ceramic Ball Head 12/14 ø 40 Size M 0 |
| 01.29.214 | BIOLOX Delta Ceramic Ball Head 12/14 ø 40 Size L +4 |
| 01.29.215 | BIOLOX Delta Ceramic Ball Head 12/14 ø 40 Size XL +8 |
| 01.29.216 | BIOLOX Delta Ceramic Ball Head 12/14 ø 44 Size S -4 |

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| 01.29.217 | BIOLOX Delta Ceramic Ball Head 12/14 ø 44 Size M 0 |
| 01.29.218 | BIOLOX Delta Ceramic Ball Head 12/14 ø 44 Size L + 4 |
| 01.29.219 | BIOLOX Delta Ceramic Ball Head 12/14 ø 44 Size XL +8 |
| 01.29.230H | Head Biolox Option ø 28 |
| 01.29.231H | Head Biolox Option ø 32 |
| 01.29.232H | Head Biolox Option ø 36 |
| 01.29.233H | Head Biolox Option ø 40 |
| 01.29.234H | Head Biolox Option ø 44 |
| 01.29.240A | Sleeve Size S |
| 01.29.241A | Sleeve Size M |
| 01.29.242A | Sleeve Size L |
| 01.29.243A | Sleeve Size XL |
| 01.29.235H | Head Biolox Option ø 48 |

The medical devices above mentioned are classified into class III as per rule 8 of European Directive 93/42/CEE annex IX emended by directive 2005/50/CE, because are part of a total hip prosthesis system.

The medical devices above are carried out applying Directive 93/42/EEC (and following modification) Annex II, as per conformity certificate nr. 29022-A and 29022-D released by Notified Body 0476_Kiwa Cermet Italia S.p.A.

MEDACTA INTERNATIONAL SA declares, under its own responsibility:

That the medical devices mentioned above comply with the essential requirements of Annex I of the European Directive 93/42/EEC and following modifications.

That the medical devices mentioned above do not incorporate, as an integral part, a substance or human blood derivate referred to in section 7.4 of Annex I of the European Directive 93/42/EEC.

That the medical devices mentioned above are not manufactured utilizing tissues of animal origin as referred to in the European Directive 2003/32/EC.

That the medical devices mentioned above do not incorporate as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC.

That standards and document claimed are listed in the design technical file. The design technical file is archived under the responsibility of the Quality Assurance Manager.

MEDACTA INTERNATIONAL SA furthermore declares, under its own responsibility, that procedures have been put in place to guarantee the post-market surveillance and product traceability.

Medacta presents a quality system management as per standard ISO 9001 nr. FM 656512 released by Notified Body 0086 BSI and ISO 13485 nr. MD 659534 released by Notified Body 0086 BSI

First issue: September 2nd 2010 (included)

Current issue: 09 Sept 2020 (included)

Independent reviewer