

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:	AI-SR-01_ BONE SCREWS
Notified Body:	0476_ Kiwa Cermet Italia S.p.A Via Cadriano, 23, 40057 Cadriano di Granarolo BO Tel 051 - 459.3.111 Fax 051.763.382

Medical devices directory codes:

Ref. No.	Description
01.43.0015	Cancellous bone screw Ø 6,5 L 15
01.43.0020	Cancellous bone screw Ø 6,5 L 20
01.43.0025	Cancellous bone screw Ø 6,5 L 25
01.43.0030	Cancellous bone screw Ø 6,5 L 30
01.43.0035	Cancellous bone screw Ø 6,5 L 35
01.43.0040	Cancellous bone screw Ø 6,5 L 40
01.43.0045	Cancellous bone screw Ø 6,5 L 45
01.43.0050	Cancellous bone screw Ø 6,5 L 50
01.43.0055	Cancellous bone screw Ø 6,5 L 55
01.43.0060	Cancellous bone screw Ø 6,5 L 60
01.43.0065	Cancellous bone screw Ø 6,5 L 65
01.43.0070	Cancellous bone screw Ø 6,5 L 70

The medical devices above mentioned are classified into class III per rule 8 of European directive 93/42/EEC annex IX, amended by directive 2005/50/CE, because are implantable medical devices part of a total joint replacing system of hip. The medical devices above are carried out applying Directive 93/42/EEC (and following modification) Annex II (including point 4) as per conformity certificate nr. 29022-A and 29022-D released by Notified Body 0476_ Kiwa Cermet Italia S.p.A.

Ref. No.	Description
01.35.125	Cortical screw rounded head - 25mm
01.35.130	Cortical screw rounded head - 30mm
01.35.135	Cortical screw rounded head - 35mm
01.35.140	Cortical screw rounded head - 40mm
01.35.145	Cortical screw rounded head - 45mm
01.35.150	Cortical screw rounded head - 50mm
01.35.155	Cortical screw rounded head - 55mm
01.35.160	Cortical screw rounded head - 60mm
01.35.165	Cortical screw rounded head - 65mm
01.35.170	Cortical screw rounded head - 70mm
01.38.220	Compression Polyaxial Locking Screw Ø6.5 – L20 mm
01.38.225	Compression Polyaxial Locking Screw Ø6.5 – L25 mm
01.38.230	Compression Polyaxial Locking Screw Ø6.5 – L30 mm
01.38.235	Compression Polyaxial Locking Screw Ø6.5 – L35 mm
01.38.240	Compression Polyaxial Locking Screw Ø6.5 – L40 mm
01.38.245	Compression Polyaxial Locking Screw Ø6.5 – L45 mm
01.38.250	Compression Polyaxial Locking Screw Ø6.5 – L50 mm
01.38.255	Compression Polyaxial Locking Screw Ø6.5 – L55 mm
01.38.260	Compression Polyaxial Locking Screw Ø6.5 – L60 mm
01.38.265	Compression Polyaxial Locking Screw Ø6.5 – L65 mm
01.38.270	Compression Polyaxial Locking Screw Ø6.5 – L70 mm

The medical devices above mentioned are classified as class IIb per rule 8 of European Directive 93/42/EEC Annex IX, as they are implantable medical devices (not part of a total joint replacement system of hip, knee and shoulder). The

medical devices above are carried out according to Directive 93/42/EEC (and all modifications) Annex II (point 4 excluded) as per conformity certificate nr. 29022-B 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 derivative 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 13485 nr. MD 659534 released by Notified Body BSI

First issue: 06-Dec-16 (included)

Current issue: May 20th 2021 (included)

Mr. G.Bussone
Independent reviewer