

Manufacturer:	implantcast GmbH Lüneburger Schanze 26 21614 Buxtehude Germany
Medical Device(s):	Bone Screw
Intended Use:	Bone screws are intended to use for screwing into the bone for primary and/or permanent stable anchorage of an implant in case of inadequate primary stability.
REF Number(s):	REF-Numbers see Attachment I - IV
Classification:	Class IIb <i>(Council Directive 93/42/EEC, Annex IX, rule 8, in conjunction with commission directive 2005/50/EC)</i>
Standard(s) applied:	
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971	Medical devices - Application of risk management to medical devices
EN ISO 11137-1	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11607-1	Packaging for terminally sterilized medical devices – Requirements for materials, sterile barrier systems and packaging systems
EN ISO 10993-1	Biological evaluation of medical devices – Part1: Evaluation and testing
EN ISO 14630	Non-active surgical implants - General requirements
EN ISO 21534	Non-active surgical implants - Joint replacement implants - Particular requirements
GMDN code(s) and term(s):	
P 46646	Orthopaedic bone screw, non-bioabsorbable, sterile

We declare under our sole responsibility that the medical device specified above are in conformity with the essential requirements listed in Annex I of Council Directive 93/42/EEC and has been gone through the conformity assessment procedure according to Annex II of Council Directive 93/42/EEC.

Notified Body: MEDCERT GmbH
Pilatuspool 2
20355 Hamburg
Germany

EC Certificate of Conformity Council Directive 93/42/EEC Annex II excluding section 4
Certificate No.: 7092GB410201201A
Validity: 01/12/2020 - 27/05/2024

Identification:

CE 0482



Buxtehude, 03.12.2020
Place, date

i.V. Juliane Höppner
Head of Regulatory Affairs

EU Declaration of Conformity

Attachment I

Reference number	item description	size	GMDN	GTIN
57934026	cancellous screw	Ø 4,0 x 26mm	P 46646	4048844051051
57934028	cancellous screw	Ø 4,0 x 28mm	P 46646	4048844051068
57934030	cancellous screw	Ø 4,0 x 30mm	P 46646	4048844051075
57934032	cancellous screw	Ø 4,0 x 32mm	P 46646	4048844051082
57934034	cancellous screw	Ø 4,0 x 34mm	P 46646	4048844051099
57924525	cortical screw	Ø 4,5 x 25 mm	P 46646	4048844101961
57924530	cortical screw	Ø 4,5 x 30 mm	P 46646	4048844050955
57924535	cortical screw	Ø 4,5 x 35 mm	P 46646	4048844101978
57924540	cortical screw	Ø 4,5 x 40 mm	P 46646	4048844050962
57924545	cortical screw	Ø 4,5 x 45 mm	P 46646	4048844101985
57924550	cortical screw	Ø 4,5 x 50 mm	P 46646	4048844050986
57924555	cortical screw	Ø 4,5 x 55 mm	P 46646	4048844101992
57924560	cortical screw	Ø 4,5 x 60 mm	P 46646	4048844102005
57923510	cortical screw	Ø 3,5 x 10 mm	P 46646	4048844305703
57923512	cortical screw	Ø 3,5 x 12 mm	P 46646	4048844305710
57923514	cortical screw	Ø 3,5 x 14 mm	P 46646	4048844305727
57923516	cortical screw	Ø 3,5 x 16 mm	P 46646	4048844305734
57923518	cortical screw	Ø 3,5 x 18 mm	P 46646	4048844305741
57923520	cortical screw	Ø 3,5 x 20 mm	P 46646	4048844305758
57923522	cortical screw	Ø 3,5 x 22 mm	P 46646	4048844305765
57923526	cortical screw	Ø 3,5 x 26 mm	P 46646	4048844305772
57923528	cortical screw	Ø 3,5 x 28 mm	P 46646	4048844305789
57923532	cortical screw	Ø 3,5 x 32 mm	P 46646	4048844305796
57923534	cortical screw	Ø 3,5 x 34 mm	P 46646	4048844305802
57923536	cortical screw	Ø 3,5 x 36 mm	P 46646	4048844305819
57923538	cortical screw	Ø 3,5 x 38 mm	P 46646	4048844306281

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Attachment II

Reference number	item description	size	GMDN	GTIN
57923545	cortical screw	Ø 3,5 x 45 mm	P 46646	4048844306304
57923555	cortical screw	Ø 3,5 x 55 mm	P 46646	4048844306311
57923560	cortical screw	Ø 3,5 x 60 mm	P 46646	4048844306328
57923565	cortical screw	Ø 3,5 x 65 mm	P 46646	4048844306335
57923570	cortical screw	Ø 3,5 x 70 mm	P 46646	4048844306342
57923575	cortical screw	Ø 3,5 x 75 mm	P 46646	4048844306359
57923580	cortical screw	Ø 3,5 x 80 mm	P 46646	4048844306366
57923585	cortical screw	Ø 3,5 x 85 mm	P 46646	4048844306373
57923590	cortical screw	Ø 3,5 x 90 mm	P 46646	4048844306380
57923595	cortical screw	Ø 3,5 x 95 mm	P 46646	4048844306397
579235100	cortical screw	Ø 3,5 x 100 mm	P 46646	4048844306403
579235105	cortical screw	Ø 3,5 x 105 mm	P 46646	4048844306410
579235110	cortical screw	Ø 3,5 x 110 mm	P 46646	4048844306427
579235115	cortical screw	Ø 3,5 x 115 mm	P 46646	4048844306434
579235120	cortical screw	Ø 3,5 x 120 mm	P 46646	4048844306441
02801015	spongiosa screw flat head	Ø 6,5 x 15 mm	P 46646	4048844006358
02801020	spongiosa screw flat head	Ø 6,5 x 20 mm	P 46646	4048844006365
02801025	spongiosa screw flat head	Ø 6,5 x 25 mm	P 46646	4048844006372
02801030	spongiosa screw flat head	Ø 6,5 x 30 mm	P 46646	4048844006389
02801035	spongiosa screw flat head	Ø 6,5 x 35 mm	P 46646	4048844006396
02801040	spongiosa screw flat head	Ø 6,5 x 40 mm	P 46646	4048844006402
02801045	spongiosa screw flat head	Ø 6,5 x 45 mm	P 46646	4048844006419
02801050	spongiosa screw flat head	Ø 6,5 x 50 mm	P 46646	4048844006426
02801055	spongiosa screw flat head	Ø 6,5 x 55 mm	P 46646	4048844006433
02801060	spongiosa screw flat head	Ø 6,5 x 60 mm	P 46646	4048844276430
02801065	spongiosa screw flat head	Ø 6,5 x 65 mm	P 46646	4048844248116
02801070	spongiosa screw flat head	Ø 6,5 x 70 mm	P 46646	4048844276751

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Attachment III

Reference number	item description	size	GMDN	GTIN
02801075	spongiosa screw flat head	Ø 6,5 x 75 mm	P 46646	4048844248130
02801080	spongiosa screw flat head	Ø 6,5 x 80 mm	P 46646	4048844248147
57936525	cancellous screw	Ø 6,5 x 25 mm	P 46646	4048844051105
57936530	cancellous screw	Ø 6,5 x 30 mm	P 46646	4048844051112
57936535	cancellous screw	Ø 6,5 x 35 mm	P 46646	4048844051129
57936540	cancellous screw	Ø 6,5 x 40 mm	P 46646	4048844051136
57936545	cancellous screw	Ø 6,5 x 45 mm	P 46646	4048844051143
57936550	cancellous screw	Ø 6,5 x 50 mm	P 46646	4048844051150
57936555	cancellous screw	Ø 6,5 x 55 mm	P 46646	4048844051167
57936560	cancellous screw	Ø 6,5 x 60 mm	P 46646	4048844051174
57944210	cancellous screw angle stable	Ø 4,2 x 10mm	P 46646	4048844104900
57944212	cancellous screw angle stable	Ø 4,2 x 12mm	P 46646	4048844104917
57944214	cancellous screw angle stable	Ø 4,2 x 14mm	P 46646	4048844104924
57944216	cancellous screw angle stable	Ø 4,2 x 16mm	P 46646	4048844104931
57944218	cancellous screw angle stable	Ø 4,2 x 18mm	P 46646	4048844104948
57944220	cancellous screw angle stable	Ø 4,2 x 20mm	P 46646	4048844104955
57944222	cancellous screw angle stable	Ø 4,2 x 22mm	P 46646	4048844104962
57944224	cancellous screw angle stable	Ø 4,2 x 24mm	P 46646	4048844104979
57944226	cancellous screw angle stable	Ø 4,2 x 26mm	P 46646	4048844104986
57944228	cancellous screw angle stable	Ø 4,2 x 28mm	P 46646	4048844104993
57944230	cancellous screw angle stable	Ø 4,2 x 30mm	P 46646	4048844105006
57944232	cancellous screw angle stable	Ø 4,2 x 32mm	P 46646	4048844105013
57944234	cancellous screw angle stable	Ø 4,2 x 34mm	P 46646	4048844105020
57944236	cancellous screw angle stable	Ø 4,2 x 36mm	P 46646	4048844105037
57944238	cancellous screw angle stable	Ø 4,2 x 38mm	P 46646	4048844105044
57944240	cancellous screw angle stable	Ø 4,2 x 40mm	P 46646	4048844105051

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Attachment IV

Reference number	item description	size	GMDN	GTIN
02870070	cancellous screw	Ø 8 x 70mm	P 46646	4048844009182
02870080	cancellous screw	Ø 8 x 80mm	P 46646	4048844009199
02870090	cancellous screw	Ø 8 x 90mm	P 46646	4048844009205
02870100	cancellous screw	Ø 8 x 100mm	P 46646	4048844009212

End of schedule. No additional information past this point.