



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Certificate - Full Quality Assurance System No. 17 0351 QS/NB

The quality system of manufacturer

Einco Biomaterial LTD.

**André Cavalcanti street – number 63- Gutierrez – Belo Horizonte –
Minas Gerais, Brazil, Zip code: 30441-025**

has been certified as meeting the requirements of

Directive 93/42/EEC

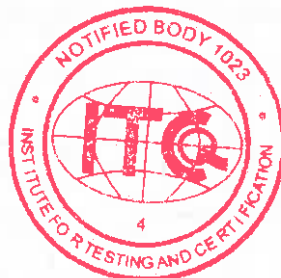
on medical devices, Annex II excluding (4)

for the following product category(ies):


Micro-Macro Porous Biphasic Calcium Phosphate Bioceramic for Bone Reconstruction

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of Class III devices covered by this certificate, an EC Design-Examination Certificate according to Annex II (Section 4) is required.

Valid from: 2017-07-31
Valid until: 2022-07-30
First Issued: 2017-07-31
Revision: -



Date: 2017-07-31


RNDr. Radomír Čevělík
Representative of the Notified Body No. 1023



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Annex to EC Certificate No. 17 0351 QS/NB
issued for manufacturer:

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Product(s):

Name: **Micro-Macro Porous Biphasic Calcium**
Phosphate Bioceramic for Bone
Reconstruction

Trade name(s): Osteosynt®

Model(s): see tables on next pages

Class: III


GMDN: 17751

Facility(ies):

Einco Biomaterial LTD.
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OSTEOSYNT Dental Use Porous Granules Periodontal Use Dental implants

Dimension	Quant. envelop	Code
10 - 20 mesh	0,5g *	OSGD 0,5 [10:20]
	1,0g	OSGD 1 [10:20]
20 - 40 mesh	0,5g *	OSGD 0,5 [20:40]
	1,0g	OSGD 1 [20:40]
40 - 60 mesh	0,5g*	OSGD 0,5 [40:60]
	1,0g	OSGD 1 [40:60]
60 - 80 mesh	0,5g *	OSGD 0,5 [60:80]
	1,0g	OSGD 1 [60:80]
80 - 100 mesh	0,5g *	OSGD 0,5 [80:100]
	1,0g	OSGD 1 [80:100]
100 - 200 mesh **	0,5g *	OSGD 0,5 [100:200]
	1,0g	OSGD 1 [100:200]



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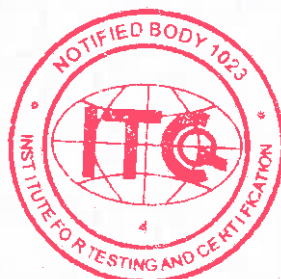
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b) General Appliances

Dimension	Quant. envelop	Code
5 - 10 mesh	2g	OSGP 2 [5:10]
	5g	OSGP 5 [5:10]
	10g	OSGP 10 [5:10]
10 - 20 mesh	2g	OSGP 2 [10:20]
	5g	OSGP 5 [10:20]
	10g	OSGP 10 [10:20]
20 - 40 mesh	2g	OSGP 2 [20:40]
	5g	OSGP 5 [20:40]
	10g	OSGP 10 [20:40]
40 - 60 mesh	2g	OSGP 2 [40:60]
	5g	OSGP 5 [40:60]
	10g	OSGP 10 [40:60]
60 - 80 mesh **	2g	OSGP 2 [60:80]
	5g	OSGP 5 [60:80]
	10g	OSGP 10 [60:80]
80 - 100 mesh	2g	OSGP 2 [80:100]
	5g	OSGP 5 [80:100]
	10g	OSGP 10 [80:100]
200-400 mesh	2g	OSGP 2 [200:400]
	5g	OSGP 5 [200:400]
	10g	OSGP 10 [200:400]
100 - 200 mesh	0,5g	OSGI 0,5 [100:200]
	1g	OSGI 1 [100:200]
	2g	OSGI 2 [100:200]
	5g	OSGI 5 [100:200]
	10g	OSGI 10 [100:200]

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c) Block - neurosurgery

Dimenzion	Quant. envelope	Code
6x4x10x12 mm segment	01 unit	OSTC 6.4.10.12
6x4x12x12 mm segment		OSTC 6.4.12.12
6x4x14x12 mm segment		OSTC 6.4.14.12
8x6x10x12 mm segment	01 unit	OSTC 8.6.10.12
8x6x12x12 mm segment		OSTC 8.6.12.12
8x6x14x12 mm segment		OSTC 8.6.14.12
10x8x10x12 mm segment	01 unit	OSTC 10.8.10.12
10x8x12x12 mm segment		OSTC 10.8.12.12
10x8x14x12 mm segment		OSTC 10.8.14.12

d) Buttons - neurosurgery

Dimension	Quant. envelope	Code
segment 10 mm	01 unit	OSBT Ø 10mm
segment 12 mm		OSBT Ø 12mm
segment 14 mm		OSBT Ø 14mm
segment 16 mm		OSBT Ø 16mm

e) Segments - neurosurgery


Dimension	Quant. envelope	Code
2,5 x 3,5 x 10x 14 mm	01 unit	OSDI 2,5x3,5x10x14
2,5 x 4,5 x 10x 14 mm	01 unit	OSDI 2,5x4,5x10x14

f) General appliance Porous sphere

Dimension	Quant. envelope	Code
Sphere 14 mm	01	OSEP Ø 14 mm
Sphere 16 mm		OSEP Ø 16 mm
Sphere 18 mm		OSEP Ø 18 mm
Sphere 20 mm		OSEP Ø 20 mm

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Porous Block

Dimension	Quant. envelope	Code
Segment 5x5x5 mm	01	OSBP 5.5.5
Segment 8x10x12 mm		OSBP 8.10.12
Segment 5x10x20 mm		OSBP 5.10.20
Segment 8x12x20 mm		OSBP 8.12.20
Segment 10x15x25 mm		OSBP 15.15.25

Porous wedge

Dimension	Quant. envelope	Code
Segment 6x8x10x12mm	01	OSBC 6.8.10.12
Segment 6x8x12x20 mm		OSBC 6.8.12.20
Segment 8x10x15x25 mm		OSBC 8.10.15.25
Segment 3x5x15x10 mm		OSBC 3.5.15.10
Segment 3x7,5x15x20 mm		OSBC 3.7,5.15.20
Segment 3x10x15x25 mm		OSBC 3.10.15.25
Segment 3x12,5x15x35 mm		OSBC 3.12,5.15.35
Segment 3x15x15x45 mm		OSBC 3.15.15.45


g) BUCO-MAXILO

Dimension	Quant. envelope	Code
Segment 8x15x25 mm	01	OSBM 8.15.25
Segment 10x10x10 mm		OSBM 10.10.10
Segment 10x10x40 mm		OSBM 10.10.40
Segment 6x15x50 mm		OSBM 6.15.50



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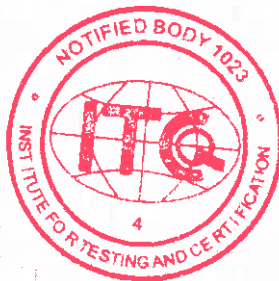
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Certificate History:

Revision	Date	Reference Number	Action
	2017-07-31	803602552	Certification



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