

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. **CE 631023**
Issued To: **Orthogem Ltd**
BioCity
Pennyfoot Street
Nottingham
NG1 1GF
United Kingdom

In respect of:

Synthetic bone graft substitute granules
Synthetic bone graft substitute putty

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Albert Roossien, Regulatory Lead

First Issued: **2015-11-11**

Date: **2019-02-21**

Expiry Date: **2021-04-18**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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Supplementary Information to CE 631023

Issued To:

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Description	Pack or Size	Catalogue Reference			
		TriPore HA	TriPore BP90	TriPore BP15	TriPore TCP
Granules 0.25-0.5mm	0.5cc	1105-0505	1605-0505	1505-0505	1305-0505
Granules 0.25-0.5mm	1.0cc	1105-0510	1605-0510	1505-0510	1305-0510
Granules 0.25-0.5mm	1.5cc	1105-0515	1605-0515	1505-0515	1305-0515
Granules 0.5-0.85mm	0.5cc	1105-0805	1605-0805	1505-0805	1305-0805
Granules 0.5-0.85mm	1.0cc	1105-0810	1605-0810	1505-0810	1305-0810
Granules 0.5-0.85mm	1.5cc	1105-0815	1605-0815	1505-0815	1305-0815
Granules 0.5-0.85mm	2.0cc	1105-0820	1605-0820	1505-0820	1305-0820
Granules 0.5-0.85mm	2cc	1104-0802	1604-0802	1504-0802	1304-0802
Granules 0.5-0.85mm	5cc	1104-0805	1604-0805	1504-0805	1304-0805
Granules 1-2mm	1.0cc	1105-1210	1605-1210	1505-1210	1305-1210
Granules 1-2mm	1.5cc	1105-1215	1605-1215	1505-1215	1305-1215

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Granules 1-2mm	2.0cc	1105-1220	1605-1220	1505-1220	1305-1220
Granules 1-2mm	2cc	1104-1202	1604-1202	1504-1202	1304-1202
Granules 1-2mm	5cc	1104-1205	1604-1205	1504-1205	1304-1205
Granules 1-2mm	10cc	1103-1210	1603-1210	1503-1210	1303-1210
Granules 1-2mm	15cc	1103-1215	1603-1215	1503-1215	1303-1215
Granules 2-4mm	5cc	1104-2405	1604-2405	1504-2405	1304-2405
Granules 2-4mm	10cc	1103-2410	1603-2410	1503-2410	1303-2410
Granules 2-4mm	15cc	1103-2415	1603-2415	1503-2415	1303-2415
Granules 2-4mm	20cc	1103-2420	1603-2420	1503-2420	1303-2420
Granules 2-4mm	30cc	1103-2430	1603-2430	1503-2430	1303-2430
Block Size 1	5cc	3107-0001	3607-0001	3507-0001	3307-0001

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Description	Pack or Size	Catalogue Reference			
		TriPore HA	TriPore BP90	TriPore BP15	TriPore TCP
Block Size 2	10cc	3107-0002	3607-0002	3507-0002	3307-0002
Block Size 3	10cc	3107-0003	3607-0003	3507-0003	3307-0003
Granules in MPA 1-2mm	8cc	1102-1208A	1602-1208A	1502-1208A	1302-1208A
Granules in MPA 1-2mm	12cc	1102-1212A	1602-1212A	1502-1212A	1302-1212A
Granules in MPA 1-4mm	8cc	1102-1408A	1602-1408A	1502-1408A	1302-1408A
Granules in MPA 1-4mm	12cc	1102-1412A	1602-1412A	1502-1412A	1302-1412A
Granules in Poloxamer (1 – 2 mm)	5cc	2102-1205			
Granules in Poloxamer (1 -2 mm)	10cc	2102-1210			

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Certificate History

Date	Reference Number	Action
11 November 2015	10153779	First issue. Transfer from another Notified Body. Design change from TDD applicator to MPA applicator. Removal of CellMix and associated product codes. Addition of MPA product codes.
11 May 2016	10161018	Certificate renewal.
26 September 2017	8570841	Scope extension – Granules in Poloxamer (2102 -1205 & 2102 – 1210).
Current	8290983	Traceable to NB 0086.

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