

EC Design-Examination Certificate

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

No.**CE 656055****Issued To:**

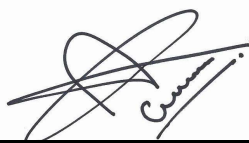
Tecres S.p.A.
Via Andrea Doria, 6
Sommacampagna (VR)
37066
Italy

In respect of:

See certificate scope page.

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: **2017-03-19**

Date: **2019-02-22**

Expiry Date: **2022-03-19**

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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.

Certificate No: CE 656055

Certificate Scope:

Bone Cement with Gentamicin**- Cemex Genta****- Bone Cement Genta****Bone Cement with Gentamicin and Vancomycin****- Vancogenx****Spacer with Gentamicin****- Spacer-G****- Spacer-K****- Spacer-S****Spacer with Gentamicin and Vancomycin****- Vancogenx-Space Hip****- Vancogenx-Space Knee****Acrylic Resin for Cranioplasty – Mendec Cranio****Bone Void filler - CAL-CEMEX**First Issued: **2017-03-19**Date: **2019-02-22**Expiry Date: **2022-03-19**

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Supplementary Information to CE 656055

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Product Code	Description
CEMEX GENTA	
1400/AG	CEMEX GENTA Low Viscosity
1400/IG	CEMEX GENTA High Viscosity
12A3100	CEMEX GENTA FAST
1400/AG INT	CEMEX GENTA LV GAMMA
1400/IG INT	CEMEX GENTA HV GAMMA
12A2420	CEMEX GENTA ID GREEN
12A2400	CEMEX GENTA ID LV
12A2410	CEMEX GENTA ID HV
1310/SG	CEMEX GENTA SYSTEM 60 g
1500/SG	CEMEX GENTA SYSTEM 80 g
13A2100	CEMEX SYSTEM GENTA FAST 70g
13A2110	CEMEX SYSTEM GENTA FAST 40g
13A2400	CEMEX SYSTEM ID GENTA 60g
13A2410	CEMEX SYSTEM ID GENTA 80g
13A2420	CEMEX SYSTEM GENTA ID GREEN 70g
13A2430	CEMEX SYSTEM GENTA ID GREEN 40g

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Product Code	Description
BONE CEMENT GENTA	
12A2100	BONE CEMENT GENTA LV
12A2110	BONE CEMENT GENTA HV
VANCOGENX	
12A2520	VANCOGENX
12A2500	VANCOGENX 1
12A2510	VANCOGENX 2
12A2530	VANCOGENX HV
SPACER-G	
SPC42/G	SPACER-G 42
SPC46/G	SPACER-G 46
SPC54/G	SPACER-G 54
SPC60/G	SPACER-G 60
SPC42/GXL	SPACER-G 42 XL
SPC46/GXL	SPACER-G 46 XL
SPC54/GXL	SPACER-G 54 XL
SPC60/GXL	SPACER-G 60 XL

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Product Code	Description
SPC1220	SPACER-G FLAT 42
SPC0620	SPACER-G FLAT 46
SPC0720	SPACER-G FLAT 54
SPC0820	SPACER-G FLAT 60
SPC1420	SPACER-G FLAT 42 XL
SPC0920	SPACER-G FLAT 46 XL
SPC1020	SPACER-G FLAT 54 XL
SPC1120	SPACER-G FLAT 60 XL
SPC0640	SPACER-G FLAT 46 ID GREEN
SPC0740	SPACER-G FLAT 54 ID GREEN
SPC0840	SPACER-G FLAT 60 ID GREEN
SPC0940	SPACER-G FLAT 46 XL ID GREEN
SPC1040	SPACER-G FLAT 54 XL ID GREEN
SPC1140	SPACER-G FLAT 60 XL ID GREEN
SPACER-K	
SPK6054/G	SPACER-K 6054
SPK7064/G	SPACER-K 7064

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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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Product Code	Description
SPK8074/G	SPACER-K 8074
SPACER-S	
SPS0020	Spacer-S 41
SPS46/G	Spacer-S 46
VANCOGENX-SPACE HIP	
SPC0030	VANCOGENX-SPACE HIP 46
SPC0130	VANCOGENX-SPACE HIP 54
SPC0230	VANCOGENX-SPACE HIP 60
SPC0330	VANCOGENX-SPACE HIP 46XL
SPC0430	VANCOGENX-SPACE HIP 54XL
SPC0530	VANCOGENX-SPACE HIP 60XL
SPC0630	VANCOGENX-SPACE HIP FLAT STEM 46
SPC0730	VANCOGENX-SPACE HIP FLAT STEM 54
SPC0830	VANCOGENX-SPACE HIP FLAT STEM 60
SPC0930	VANCOGENX-SPACE HIP FLAT STEM 46XL
SPC1030	VANCOGENX-SPACE HIP FLAT STEM 54XL
SPC1130	VANCOGENX-SPACE HIP FLAT STEM 60XL

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Product Code	Description
VANCOGENX-SPACE KNEE	
SPK0030	VANCOGENX-SPACE KNEE 6054
SPK0130	VANCOGENX-SPACE KNEE 7064
SPK0230	VANCOGENX-SPACE KNEE 8074
SPK0330	VANCOGENX-SPACE KNEE 9084
MENDEC CRANIO	
1220/D	MENDEC CRANIO (radiopaque)
1220/N	MENDEC CRANIO (non radiopaque)
CAL-CEMEX	
13A6000	CAL-CEMEX
MectaCem Genta	
65.01.014	MectaCem II LV with Gentamicin
65.01.012	MectaCem II HV with Gentamicin

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Certificate History

Date	Reference Number	Action
19 March 2017	10164005	First Issue Transfer from another Notified Body Certificate Renewal
04 August 2017	8744025	Addition of Vancogenx HV 12A2530
27 March 2018	8918334	Certificate re-issue to correct BSI template to address route of conformity 93/42/EEC Annex II, Section 4 (2007/47).
20 February 2019	9627179	Approval of new packaging configuration for the product, Bone Cement Genta LV 40g and Bone Cement Genta HV 40g , product codes 12A2100 and 12A2110 Approval of new shelf-life for the product Bone Cement Genta LV 40g and Bone Cement Genta HV 40g, product codes 12A2100 and 12A2110 Addition of new part numbers/descriptions; MectaCem II LV with Genta – Part No: 65.01.014 and MectaCem II HV with Genta – Part No: 65.01.012.
Current	8716925	Traceable to NB 0086.

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