

EC CERTIFICATE

Annex II excluding section 4 of the Directive 93/42/EEC on Medical Devices

Full Quality Assurance System

Certificate Number

CE-MDD-0100/12/2020/01

Manufacturer : Bonegraft Biyolojik Malzemeler San. ve Tic. A.S.

Address(es) : **Headquarters:** Ege Universitesi Sit. Ideege Teknoloji Gelistirme Bolgesi A.S. Erzene Mah. Ankara Cad. 172/67 Bornova/ Izmir / TURKEY - P.C. 35100.**Production:** Kecilikoy OSB Mahallesi Ismail Kahraman Cad. No:1/1/A Yunusemre / Manisa / TURKEY- P.C. 45030**Branch Office:** Kemalpaşa Mahallesi 7410 Sokak No:8 Pınarbaşı Bornova / Izmir / TURKEY P.C.35060

Product(s) : Sterile PMMA(Polymethyl Methacrylate) Bone Cement

Brand Name: Powerbone, Bonegraft, Ecobone, Biongraft, Triabone, I-BONE, Osteon, Ligamed, Orthobion, NET, KAULMED, fX, BonetechModel(s) : Please see 2nd page for product of models.

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NOTICE, Notified Body 2764, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC and unannounced audits. NOTICE must be informed of any significant changes in the design and/or construction of the product(s).

Özlem Vicdan Akdağ
Chairman**NOTİCE BELGELENDİRME
MUAYENE VE DENETİM
HİZMETLERİ A.Ş.**Esentepe Mahallesi Milangaz Caddesi
No:75/A/92 Kartal / İstanbul / TÜRKİYE
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Product Name	Model Name	Sub-Model Name	Weight
Sterile PMMA (Polymethyl Methacrylate) Bone Cement	Low Viscosity	Radiopaque Vertebroplasty Bone Cement, PMMA, 20 g	20 g
		Radiopaque Vertebroplasty Bone Cement, PMMA, 40 g	40 g
		Radiopaque Kyphoplasty Bone Cement, PMMA, 20 g	20 g
		Radiopaque Kyphoplasty Bone Cement, PMMA, 40 g	40 g
		Radiopaque Bone Cement, PMMA, 20 g	20 g
		Radiopaque Bone Cement, PMMA, 40 g	40 g
	Standard Viscosity	Radiopaque Vertebroplasty Bone Cement, PMMA, 40 g	40 g
		Radiopaque Kyphoplasty Bone Cement, PMMA, 40 g	40 g
		Radiopaque Bone Cement-Normal, PMMA, 40 g	40 g
		Radiopaque Bone Cement-Normal, PMMA, 60 g	60 g
		Radiopaque Bone Cement, PMMA	40 g
	High Viscosity	Radiopaque Bone Cement, PMMA	40 g

