

**FSN REF: 01/2023**  
**FSCA REF: 230307****ADDENDUM**  
**URGENT FIELD SAFETY NOTICE**Data: 17/03/2023  
Date: 17/03/2023

Nome commerciale del dispositivo: BIO-GEN<sup>®</sup>  
Variante del dispositivo: GRANULI  
*Campo di applicazione: chirurgia dentale*  
Commercial name of the device: BIO-GEN<sup>®</sup>  
Variant of the device: GRANULES  
*FIELD of USE: dental surgery*

**All'attenzione di:** Ministero della Salute Italiano,  
Ufficio 5, Direzione generale dei dispositivi medici e del servizio farmaceutico (DGDMF),  
**To the attention of:** Italian Ministry of Health,  
Office 5, General Directorate of Medical Devices and Pharmaceutical Service,

Viale Giorgio Ribotta, 5 - 00144 Roma  
Telefono/Phone: 06 5994 3199 - 3207  
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**Per conoscenza a:** ON0477 – Eurofins Product Testing Srl  
**For information to:** NB 0477 – Eurofins Product Testing Srl  
[tech@eurofins.com](mailto:tech@eurofins.com)

**ELENCO DEI DISPOSITIVI POTENZIALMENTE OGGETTO DELL'FSN 01/2023**  
**LIST OF DEVICES POTENTIALLY COVERED BY FSN 01/2023**

In relazione all'FSN 01/2023, emesso da Bioteck Spa in data 7/03/2023, si specifica di seguito l'elenco dei codici del Dispositivo Medico BIO-GEN<sup>®</sup>, variante GRANULI, potenzialmente colpiti dalla falsificazione.

*In relation to FSN 01/2023, issued by Bioteck Spa on 7/03/2023, we specify below the list of codes of the Medical Device BIO-GEN<sup>®</sup>, GRANULES variant, potentially affected by the falsification.*

**BIOTECK S.p.A.**

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VAT.n: IT02702750247 - CF: 06857400011 - REA: VI268440 - Sh.Cap. €120.000,00 i.v.

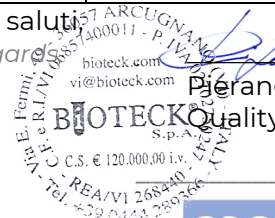
**Production Facility:** Via G. Agnelli, 3 - 10020 Riva presso Chieri (TO) Italy  
[www.bioteck.com](http://www.bioteck.com)

REF	GTIN Code	REF_DESCRIPTION	Extended description
<b>BGC-05</b>	8056518500312	BIO-GEN Cortical Bone Granules	Cortical Granules - 6 btl / 0.5g 0.25-1mm
<b>BGC-05s</b>	8056518500169	BIO-GEN Cortical Bone Granules	Cortical Granules - 1 btl / 0.5g 0.25-1mm
<b>BGM-05</b>	8056518500336	BIO-GEN Mix Granules	Cancellous Cortical Granules - 6 btl / 0.5g 0.25-1mm
<b>BGM-05n</b>	8056518500343	BIO-GEN Mix Granules	Cancellous Cortical Granules - 1 btl / 0.5g 0.25-1mm
<b>BGM-05s</b>	8056518500176	BIO-GEN Mix Granules	Cancellous Cortical Granules - 1 btl / 0.5g 0.25-1mm
<b>BGM-10</b>	8056518500350	BIO-GEN Mix Granules	Cancellous Cortical Granules - 6 btl / 0.25g 0.25-1mm
<b>BGM-100</b>	8056518503832	BIO-GEN Mix Granules	Cancellous Cortical Granules - 6 btl / 1g 0.25-1mm
<b>BGM-100s</b>	8056518500183	BIO-GEN Mix Granules	Cancellous Cortical Granules - 1 btl / 1g 0.25-1mm
<b>BGM-10s</b>	8056518500206	BIO-GEN Mix Granules	Cancellous Cortical Granules - 1 btl / 0.25g 0.25-1mm
<b>BGM-20</b>	8056518500367	BIO-GEN Mix Granules	Cancellous Cortical Granules - 1 btl / 2g 0.25-1mm
<b>BGS-05</b>	8056518500459	BIO-GEN Cancellous Granules	Cancellous Granules - 6 btl / 0.5g 0.25-1mm
<b>BGS-05n</b>	8056518500466	BIO-GEN Cancellous Granules	Cancellous Granules - 1 btl / 0.5g 0.25-1mm
<b>BGS-05s</b>	8056518500558	BIO-GEN Cancellous Granules	Cancellous Granules - 1 btl / 0.5g 0.25-1mm
<b>BGS-09</b>	8056518500473	BIO-GEN Cancellous Granules	Cancellous Granules - 6 btl / 0.5g 1-2mm
<b>BGS-09s</b>	8056518500596	BIO-GEN Cancellous Granules	Cancellous Granules - 1 btl / 0.5g 1-2mm
<b>BGS-10</b>	8056518500480	BIO-GEN Cancellous Granules	Cancellous Granules - 1 btl / 0.5g 1-2mm
<b>BGS-11</b>	8056518500497	BIO-GEN Cancellous Granules	Cancellous Granules - 6 btl / 1g 1-2mm
<b>BGS-11s</b>	8056518500671	BIO-GEN Cancellous Granules	Cancellous Granules - 1 btl / 1g 1-2mm
<b>BGS-20</b>	8056518500510	BIO-GEN Cancellous Granules	Cancellous Granules - 1 btl / 2g 0.25-1mm
<b>BGS-22</b>	8056518500534	BIO-GEN Cancellous Granules	Cancellous Granules - 1 btl / 2g 1-2mm.
<b>BGS-23</b>	8056518500541	BIO-GEN Cancellous Granules	Cancellous Granules - 6 btl / 1g 2-3mm
<b>BGS-23s</b>	8056518500725	BIO-GEN Cancellous Granules	Cancellous Granules - 1 btl / 1g 2-3mm

Distinti saluti

Best regards

  
**Pierangelo Di Lazzaro**  
 Quality Manager - Bioteck SpA



## BIOTECK S.p.A.

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