FSN REF: 01/2023
FSCA REF: 230307

URGENT FIELD SAFETY NOTICE

Date: 07/03/2023

Commercial name of the device: BIO-GEN®
Variant of the device: GRANULES
FIELD of USE: dental surgery

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
Fax: 06 5994 3776
E-mail: segr.dgfdm@sanita.it
PEC: dgfdm@postacert.sanita.it

For information to: NB 0477 – Eurofins Product Testing Srl
tech@eurofins.com

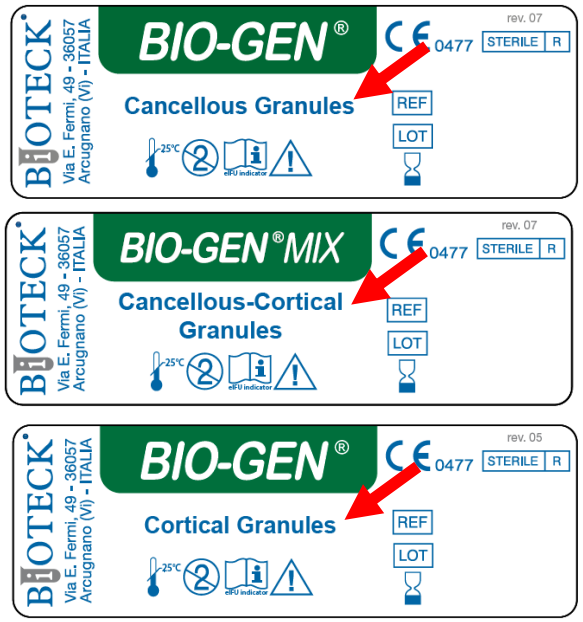
SUBJECT: FALSIFICATION OF MEDICAL DEVICES ON THE INTERNATIONAL MARKET

Bioteck SpA, as the Manufacturer of the CE-marked Medical Device BIO-GEN®, informs that it has detected the presence of FALSE packaging of the Medical Device in the variant "granules" on the territory of TURKEY.

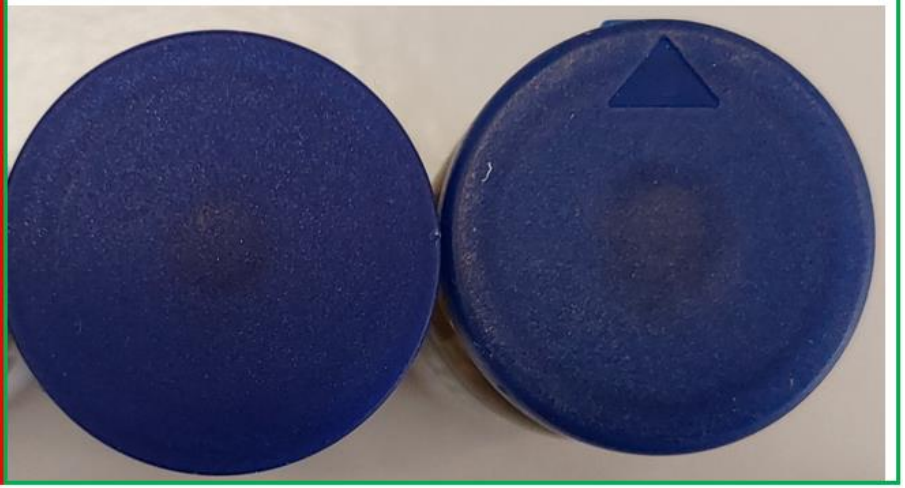
The falsification is evident in the packaging and certainly in the contents.

The falsified devices bear the name BIO-GEN® and the indication of Bioteck SpA as the manufacturer but have packaging characteristics that unmistakably distinguish them from the original devices.
The contents of the bottles are not known to Bioteck spa.

In this regard, photographic documentation is attached to aid in the identification of the falsified medical device in comparison with the one legally manufactured by Bioteck SpA.

Feature	Falsified Device	Original Device
1) Description on bottle label. The falsified device has the wording "RESORBABLE NATURAL BONE" (red arrow). In contrast, the correct wording is shown in the "Original Device" column (red arrows).		

Feature	Falsified Device	Original Device
1) Reference to NB CE on bottle label. The falsified device has the indication: 0474 (red arrow). The original device has the indication for NB 0477. For batches produced until 2019 NB is 0373.		CE 0477 or in alterntaive CE 0373

Feature	
2) Cap and bottle closure ring. The falsified device has a light blue cap with grooves along the edges (red arrows). The original device, may have two variants, both with dark blue cap, without groove. .	*Falsified device: front view*  *Original device: front view (2 variants on the market)*  *Falsified device: view from above*  *Original device: view from above (2 variants on the market)* 

Description of potential problem:
There is no guarantee of the safety and effectiveness of the product.
FALSE device and contents of the bottle NOT known.
Bioteck spa is not the manufacturer and is not responsible for the production and composition of the device.
Bioteck spa is not able to formulate any risk assessment for the user and the patient.

Actions to be taken to mitigate the risk by Bioteck:
1) send this safety notice to the competent authorities
2) send this safety notice to its distribution partners/ sales network and customers to promote the maximum diffusion thereof;
3) ask sales network for adequate attention on what is on the market.

Actions to be taken to mitigate the risk by sales network:
1) Forward this FSN to its customers (users and/or sub distributors).

Actions to be taken to mitigate the risk by the user:
Anyone who realizes that they are in possession of the falsified products should:
1) Not use the product
2) Arrange for its immediate segregation in a safe place and available for investigations, including judicial investigations
3) Give notice to the email address: pms@bioteck.com, sending photos of the falsified product, information about the quantities in your possession, and who supplied the falsified product.

Contact information of the reference person:
Marco Morroni
Direttore Affari Regolatori Bioteck SpA
Regulatory Affairs Director Bioteck SpA
Tel: +39 0444 289366
Email: pms@bioteck.com

The undersigned confirms that this notice has been served on the appropriate regulatory agencies and economic operators.

Best regards,

Pierangelo Di Lazzaro
Quality Manager

Bioteck SpA

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

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tech@eurofins.com

LIST OF DEVICES POTENTIALLY COVERED BY FSN 01/2023

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®, GRANULES variant, potentially affected by the falsification.

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

Best regards,

Pierangelo Di Lazzaro
Quality Manager - Bioteck SpA

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