

SAFETY NOTICE
CROSS-BORDER FALSIFICATION OF MEDICAL DEVICES
Fin-Ceramica Faenza

Turkish Medicines and Medical Devices Agency
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Directorate-General of medical devices and pharmaceutical services
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Autonomous Regions and Provinces

Public and private healthcare facilities

National economic operators

Notified Body 0373 – Italian National Institute of Health (ISS)

Re: Notice of falsification of medical devices manufactured by Fin-Ceramica Faenza S.p.A. and similar for type to MaioRegen (Internal Ref. NC 008/22)

Fin-Ceramica Faenza S.p.A., as the manufacturer of the medical devices, similar for type to **MaioRegen** hereby gives notice that a Turkish economic operator has communicated the existence of falsified medical devices in Turkey with falsified packaging and potentially altered contents.

At present, the presence of such falsified medical devices cannot be excluded on the Italian and European territory.

To date, the manufacturer has not been able to analyse the products subject to falsification since they are not available.

They bear the logo no longer in use but similar to the originals of the manufacturer and the name “cartilage layer”.

In this regard, we hereby include photographic evidence to facilitate the identification of the falsified medical devices compared to those originally and legally produced by Fin-Ceramica Faenza S.p.A.

FALSIFIED



ORIGINAL – Current Configuration



The falsified product, in particular the box, bears the logo of the manufacturer (Fin-Ceramica Faenza, the label of the product, the appearance and its configuration (bottle) are different from the production guaranteed by Fin-Ceramica Faenza S.p.A

Original view of both sides of the MaioRegen Prime box (labelled and unlabelled side) and the inner packaging (labelled and unlabelled side)

FALSIFIED



The falsified product, in particular the box, bears the logo of the manufacturer (Fin-Ceramica Faenza, the label of the product, the appearance and its configuration (bottle) are different from the production guaranteed by Fin-Ceramica Faenza S.p.A

ORIGINAL – Current Configuration



Original view of MaioRegen boxes (Slim e Chondro)

FALSIFIED



The falsified product, in particular the box, bears the logo of the manufactured (Fin-Ceramica Faenza, the label of the product, the appearance and its configuration (bottle) are different from the production guaranteed by Fin-Ceramica Faenza S.p.A

ORIGINAL – Configuration prior to January 2017




Original view of MayoRegen box

As a precautionary measure, we undertake to promptly inform the Ministry of Health, public and private healthcare facilities, economic operators, and the relevant Local Health Authorities (ASL).

Yours sincerely

Gianluca Fantini



14/03/2022
(Chief Executive Officer)

Operating instructions for end users:

If, in your commercial and healthcare facilities, you receive or find products believed to be falsified, or even if in doubt, these **SHOULD NOT BE USED!**

Therefore, for your safety and for the safety of patients, clearly mark the products and store them safely. Immediately contact our head office to allow the definitive recognition and collection of the above products by authorized and qualified personnel of the manufacturer.

If the falsification of products that have already been implanted is confirmed, please activate the traceability system for the identification of those patients who have received the falsified implant and send us all the relevant information. Please also inform the Ministry of Health, Regions, Autonomous Provinces, all Local Health Authorities, and the manufacturer.

Below are the manufacturer's contact details to be used for all communications:

Address: Via Ravegnana, 186 - 48018, Faenza (RA) - Italy

Tel: (+39) 0546 607311 Fax: (+39) 0546 607312

E-mail: info@finceramica.it

Certified e-mail: (only for Italy): finceramica@pec.finceramica.it

Yours sincerely

Gianluca Fantini


(Chief Executive Officer)

14/03/2022