



# CERTIFICATE

## EC Certificate Design Examination According to Medical Devices Directive 93/42/EEC Annex-II Section 4

Certificate Number: 1984-MDD-19-628

We hereby declare that a design examination has been carried out on the devices listed hereafter following the requirements of the national legislation to which the undersigned is subjected, transposing Annex II Section 4 of the Directive 93/42/EEC on medical devices. We certify that the design of the device(s) listed thereafter conforms with the relevant provisions of Annex II Section 4 of the Directive 93/42/EEC on medical devices as transposed into national legislation.

### Organization

#### SPINEART SA

Chemin du Pré-Fleuri 3, 1228 Plan-les-Ouates, Switzerland

**Product:** BGel® Synthetic Osteoconductive Gel

The products defined at the enclosure which is the part of this certificate and contains one (1) page. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Full quality assurance system according to Medical Devices Directive 93/42/EEC Annex-II Section 3 certificate is also mandatory for class III devices covered by this certificate.

**Report Number:** M.5701.01  
**Expiry Date:** 27 May 2024

29 November 2019, Istanbul, Turkey

Muhteşem Gökhan Yücel  
Head of Notified Body

Enclosure of the EC Certificate:

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Design Examination

Medical Devices Directive 93/42/EEC Annex-II Section 4

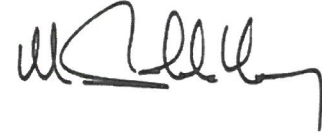
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Concerned medical devices;

Product: BGel® Synthetic Osteoconductive Gel

Reference	Models
20.00.01	βGel® synthetic osteoconductive gel Pack Volume 1 cc
20.00.25	βGel® synthetic osteoconductive gel Pack Volume 2.5cc
20.00.05	βGel® synthetic osteoconductive gel Pack Volume 5cc
20.00.10	βGel® synthetic osteoconductive gel Pack Volume 10cc

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

A handwritten signature in black ink, appearing to read "Muhteşem Gökhan Yücel".

29 November 2019, Istanbul, Turkey

Muhteşem Gökhan Yücel  
Head of Notified Body