CERTIFICATE

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

Certificate Number: 1984-MDD-21-769

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

Speciality Fibres and Materials Limited

Galaxy House 31 Herald Way Binley Industrial Estate Coventry CV3 2RQ, UK

Product: Venus Ag

The products defined at the enclosure which is the part of this certificate and contains seven (7) 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.5991.01
Expiry Date: 27 May 2024

Muhteşem Gökhan Yücel
Head of Notified Body

05 May 2021, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

CERTIFICATE

Enclosure of the EC Certificate:

Design Examination

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

Certificate Number: 1984-MDD-21-769

Concerned medical devices;

Product: Venus Ag

Product Code	Commercial Name/Dimensions
FV000001	Venus Ag 120 5x5cm
FV000002	Venus Ag 120 10x10cm
FV000003	Venus Ag 120 10x12.5cm
FV000004	Venus Ag 120 15x15cm
FV000005	Venus Ag 120 2x45
FV000006	Venus Ag 160 5x5cm
FV000007	Venus Ag 160 10x10cm
FV000008	Venus Ag 160 10x12.5cm
FV000009	Venus Ag 160 15x15cm
FV000010	Venus Ag 160 2x45
FV000011	Venus Ag 200 5x5cm
FV000012	Venus Ag 200 10x10cm
FV000013	Venus Ag 200 10x12.5cm
FV000014	Venus Ag 200 15x15cm
FV000015	Venus Ag 200 2x45

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

Muhteşem Gökhan Yücel
Head of Notified Body

05 May 2021, Istanbul, Turkey

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