

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

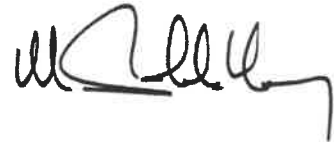
Product: Venus Ag

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.

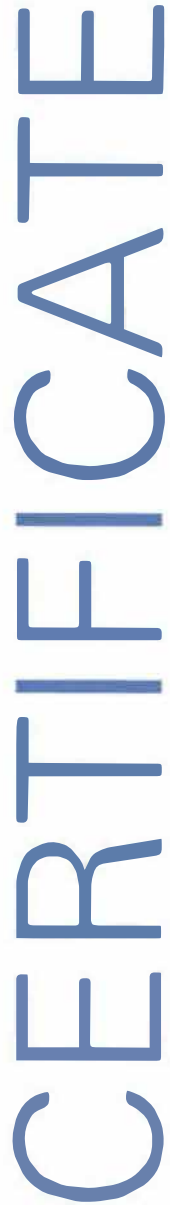
Report Number: M.5991.01

Expiry Date: 27 May 2024



Muhteşem Gökhan Yücel
Head of Notified Body

05 May 2021, Istanbul, Turkey



Design Examination

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

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Concerned medical devices;

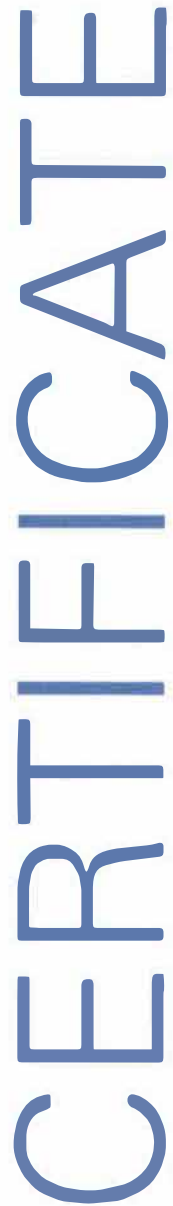
Product: Venus Ag

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W. L. L.

Muhteşem Gökhan Yücel
Head of Notified Body

05 May 2021, Istanbul, Turkey



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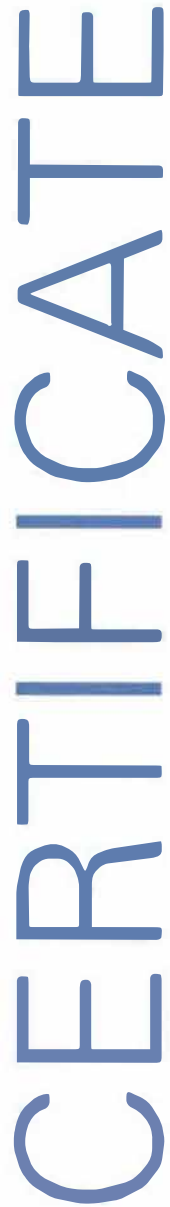
Concerned medical devices;

Product: Venus Ag[illegible]

W. L. L.

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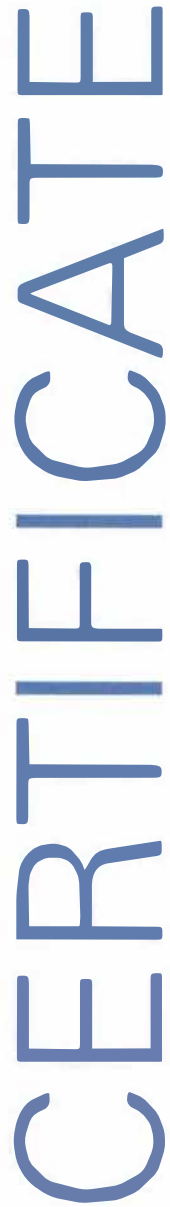
Concerned medical devices;

Product: Venus Ag[illegible]

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05 May 2021, Istanbul, Turkey



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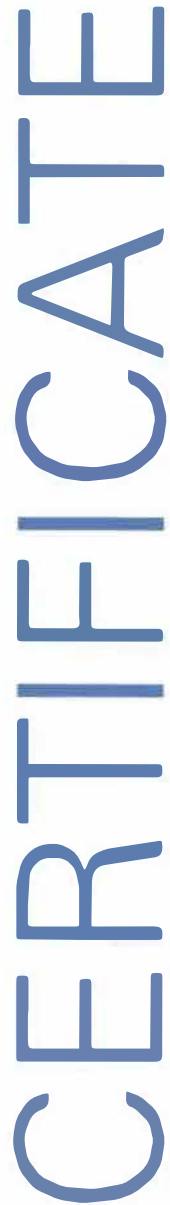
Product: Venus Ag

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Muhteşem Gökhan Yücel
Head of Notified Body

05 May 2021, Istanbul, Turkey



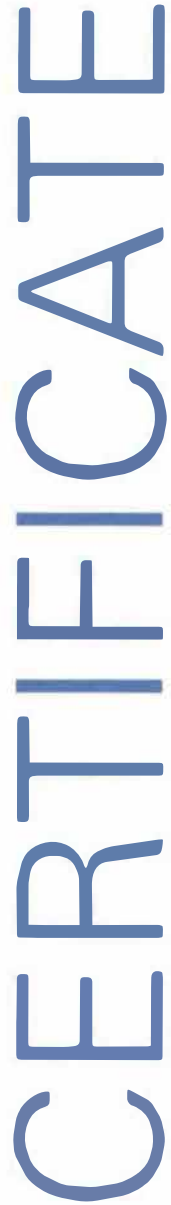
Product: Venus Ag

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Handwritten signature

05 May 2021, Istanbul, Turkey

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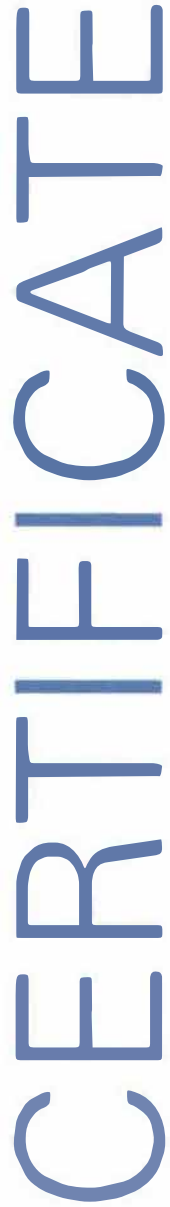
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Muhteşem Gökhan Yücel
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Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

W. L. L.

Muhteşem Gökhan Yücel
Head of Notified Body

05 May 2021, Istanbul, Turkey

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