



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



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**Design Examination**

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

**Certificate Number: 1984-MDD-21-769**

Concerned medical devices;

**Product: Venus Ag**

<b>Product Code</b>	<b>Commercial Name/Dimensions</b>
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
FV000016	ExuCel Ag 120 5x5cm
FV000017	ExuCel Ag 120 10x10cm
FV000018	ExuCel Ag 120 10x12.5cm
FV000019	ExuCel Ag 120 15x15cm
FV000020	ExuCel Ag 120 2x45
FV000021	ExuCel Ag 160 5x5cm
FV000022	ExuCel Ag 160 10x10cm
FV000023	ExuCel Ag 160 10x12.5cm
FV000024	ExuCel Ag 160 15x15cm
FV000025	ExuCel Ag 160 2x45

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Head of Notified Body

05 May 2021, Istanbul, Turkey



# CERTIFICATE

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**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
FV000026	ExuCel Ag 200 5x5cm
FV000027	ExuCel Ag 200 10x10cm
FV000028	ExuCel Ag 200 10x12.5cm
FV000029	ExuCel Ag 200 15x15cm
FV000030	ExuCel Ag 200 2x45
FV000031	ExuPro Cel Ag 120 5x5cm
FV000032	ExuPro Cel Ag 120 10x10cm
FV000033	ExuPro Cel Ag 120 10x12.5cm
FV000034	ExuPro Cel Ag 120 15x15cm
FV000035	ExuPro Cel Ag 120 2x45
FV000036	ExuPro Cel Ag 160 5x5cm
FV000037	ExuPro Cel Ag 160 10x10cm
FV000038	ExuPro Cel Ag 160 10x12.5cm
FV000039	ExuPro Cel Ag 160 15x15cm
FV000040	ExuPro Cel Ag 160 2x45
FV000041	ExuPro Cel Ag 200 5x5cm
FV000042	ExuPro Cel Ag 200 10x10cm
FV000043	ExuPro Cel Ag 200 10x12.5cm
FV000044	ExuPro Cel Ag 200 15x15cm
FV000045	ExuPro Cel Ag 200 2x45
FV000046	NanoCel Ag 120 5x5cm
FV000047	NanoCel Ag 120 10x10cm
FV000048	NanoCel Ag 120 10x12.5cm
FV000049	NanoCel Ag 120 15x15cm
FV000050	NanoCel Ag 120 2x45



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**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
FV000051	NanoCel Ag 160 5x5cm
FV000052	NanoCel Ag 160 10x10cm
FV000053	NanoCel Ag 160 10x12.5cm
FV000054	NanoCel Ag 160 15x15cm
FV000055	NanoCel Ag 160 2x45
FV000056	NanoCel Ag 200 5x5cm
FV000057	NanoCel Ag 200 10x10cm
FV000058	NanoCel Ag 200 10x12.5cm
FV000059	NanoCel Ag 200 15x15cm
FV000060	NanoCel Ag 200 2x45
FV000061	LunaFiber Ag 120 5x5cm
FV000062	LunaFiber Ag 120 10x10cm
FV000063	LunaFiber Ag 120 10x12.5cm
FV000064	LunaFiber Ag 120 15x15cm
FV000065	LunaFiber Ag 120 2x45
FV000066	LunaFiber Ag 160 5x5cm
FV000067	LunaFiber Ag 160 10x10cm
FV000068	LunaFiber Ag 160 10x12.5cm
FV000069	LunaFiber Ag 160 15x15cm
FV000070	LunaFiber Ag 160 2x45
FV000071	LunaFiber Ag 200 5x5cm
FV000072	LunaFiber Ag 200 10x10cm
FV000073	LunaFiber Ag 200 10x12.5cm
FV000074	LunaFiber Ag 200 15x15cm
FV000075	LunaFiber Ag 200 2x45



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**Design Examination**

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

**Certificate Number: 1984-MDD-21-769**

Concerned medical devices;

**Product:** Venus Ag

<b>Product Code</b>	<b>Commercial Name/Dimensions</b>
FV000076	Sequana Ag 120 5x5cm
FV000077	Sequana Ag 120 10x10cm
FV000078	Sequana Ag 120 10x12.5cm
FV000079	Sequana Ag 120 15x15cm
FV000080	Sequana Ag 120 2x45
FV000081	Sequana Ag 160 5x5cm
FV000082	Sequana Ag 160 10x10cm
FV000083	Sequana Ag 160 10x12.5cm
FV000084	Sequana Ag 160 15x15cm
FV000085	Sequana Ag 160 2x45
FV000086	Sequana Ag 200 5x5cm
FV000087	Sequana Ag 200 10x10cm
FV000088	Sequana Ag 200 10x12.5cm
FV000089	Sequana Ag 200 15x15cm
FV000090	Sequana Ag 200 2x45
FV000091	SequanaCel Ag 120 5x5cm
FV000092	SequanaCel Ag 120 10x10cm
FV000093	SequanaCel Ag 120 10x12.5cm
FV000094	SequanaCel Ag 120 15x15cm
FV000095	SequanaCel Ag 120 2x45
FV000096	SequanaCel Ag 160 5x5cm
FV000097	SequanaCel Ag 160 10x10cm
FV000098	SequanaCel Ag 160 10x12.5cm
FV000099	SequanaCel Ag 160 15x15cm
FV000100	SequanaCel Ag 160 2x45



**Muhteşem Gökhan Yücel**  
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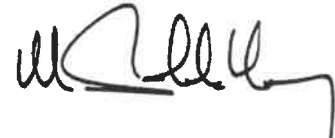
05 May 2021, Istanbul, Turkey

**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
FV000101	SequanaCel Ag 200 5x5cm
FV000102	SequanaCel Ag 200 10x10cm
FV000103	SequanaCel Ag 200 10x12.5cm
FV000104	SequanaCel Ag 200 15x15cm
FV000105	SequanaCel Ag 200 2x45
FV000106	SequanaFiber Ag 120 5x5cm
FV000107	SequanaFiber Ag 120 10x10cm
FV000108	SequanaFiber Ag 120 10x12.5cm
FV000109	SequanaFiber Ag 120 15x15cm
FV000110	SequanaFiber Ag 120 2x45
FV000111	SequanaFiber Ag 160 5x5cm
FV000112	SequanaFiber Ag 160 10x10cm
FV000113	SequanaFiber Ag 160 10x12.5cm
FV000114	SequanaFiber Ag 160 15x15cm
FV000115	SequanaFiber Ag 160 2x45
FV000116	SequanaFiber Ag 200 5x5cm
FV000117	SequanaFiber Ag 200 10x10cm
FV000118	SequanaFiber Ag 200 10x12.5cm
FV000119	SequanaFiber Ag 200 15x15cm
FV000120	SequanaFiber Ag 200 2x45
FV000121	Sirona Ag 120 5x5cm
FV000122	Sirona Ag 120 10x10cm
FV000123	Sirona Ag 120 10x12.5cm
FV000124	Sirona Ag 120 15x15cm
FV000125	Sirona Ag 120 2x45



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**Design Examination**

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Concerned medical devices;

**Product: Venus Ag**

<b>Product Code</b>	<b>Commercial Name/Dimensions</b>
FV000126	Sirona Ag 160 5x5cm
FV000127	Sirona Ag 160 10x10cm
FV000128	Sirona Ag 160 10x12.5cm
FV000129	Sirona Ag 160 15x15cm
FV000130	Sirona Ag 160 2x45
FV000131	Sirona Ag 200 5x5cm
FV000132	Sirona Ag 200 10x10cm
FV000133	Sirona Ag 200 10x12.5cm
FV000134	Sirona Ag 200 15x15cm
FV000135	Sirona Ag 200 2x45
FV000136	SironaCel Ag 120 5x5cm
FV000137	SironaCel Ag 120 10x10cm
FV000138	SironaCel Ag 120 10x12.5cm
FV000139	SironaCel Ag 120 15x15cm
FV000140	SironaCel Ag 120 2x45
FV000141	SironaCel Ag 160 5x5cm
FV000142	SironaCel Ag 160 10x10cm
FV000143	SironaCel Ag 160 10x12.5cm
FV000144	SironaCel Ag 160 15x15cm
FV000145	SironaCel Ag 160 2x45
FV000146	SironaCel Ag 200 5x5cm
FV000147	SironaCel Ag 200 10x10cm
FV000148	SironaCel Ag 200 10x12.5cm
FV000149	SironaCel Ag 200 15x15cm
FV000150	SironaCel Ag 200 2x45



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Concerned medical devices;

**Product:** Venus Ag

<b>Product Code</b>	<b>Commercial Name/Dimensions</b>
FV000151	SironaFiber Ag 120 5x5cm
FV000152	SironaFiber Ag 120 10x10cm
FV000153	SironaFiber Ag 120 10x12.5cm
FV000154	SironaFiber Ag 120 15x15cm
FV000155	SironaFiber Ag 120 2x45
FV000156	SironaFiber Ag 160 5x5cm
FV000157	SironaFiber Ag 160 10x10cm
FV000158	SironaFiber Ag 160 10x12.5cm
FV000159	SironaFiber Ag 160 15x15cm
FV000160	SironaFiber Ag 160 2x45
FV000161	SironaFiber Ag 200 5x5cm
FV000162	SironaFiber Ag 200 10x10cm
FV000163	SironaFiber Ag 200 10x12.5cm
FV000164	SironaFiber Ag 200 15x15cm
FV000165	SironaFiber Ag 200 2x45

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