CERTIFICATE

EC Certificate

Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-21-752

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

Speciality Fibres and Materials Limited

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

Products: Pluto Ag, Silver Alginate, Venus Ag

The products defined at the enclosure which is the part of this certificate and contains two (2) page. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Design Examination according to Medical Devices Directive 93/42/EEC Annex-II Section 4 certificate is also mandatory for class III devices covered by this certificate.

Report Number:	M.5991.01
Date of first issue:	16 April 2021
Date of last issue:	05 May 2021
Revision Number:	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:

Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II.3
Certificate Number: 1984-MDD-21-752, Revision Number: 01

Concerned medical devices;

Product: Pluto Ag

Models
Pluto Ag
Algipure AG Plus
AlgiWound Ultima Ag
AlgiPro Ultima Ag
ExuPro Advance Ag
SelectWound Pro Ag
SelectWound Ultima Ag
Suprasorb A+Ag Pro
CovaWound Alginate Ag+

Product: Silver Alginate

Models
Silver Alginate
Algipure AG
AlgiWound Ag
AlgiPro Ag
ExuPro Ag
SelectWound Ag
Suprasorb A+Ag
CovaWound Alginate Ag

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:

Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II.3
Certificate Number: 1984-MDD-21-752, Revision Number: 01

Concerned medical devices;

Product: Venus Ag

Models
Venus Ag
ExuCel Ag
ExuPro Cel Ag
NanoCel Ag
LunaFiber Ag
Sequana Ag
SequanaCel Ag
SequanaFiber Ag
Sirona Ag
SironaCel Ag
SironaFiber Ag

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

05 May 2021, Istanbul, Turkey

Muhteşem Gökhan Yücel
Head of Notified Body

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