CERTIFICATE

EC Certificate

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

Certificate Number: 1984-MDD-20-687

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:

VSY BIOTECHNOLOGY GmbH

Esslinger Str.7, 70771 Leinfelden – Echterdingen GERMANY

Products: Intraocular Lenses, Intraocular Lenses (Preloaded), Ophthalmic Viscosurgical Medical Devices, Cartridge & Injector for Ophthalmology, Intraarticular Viscosupplementation Medical Devices

The products defined at the enclosure which is the part of this certificate and contains four (4) pages. 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.5810.01
Expiry Date: 27 May 2024

Muhteşem Gökhan Yücel
Head of Notified Body

24 July 2020, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
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Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com

Digitally signed by Jechiu Cristina
Date: 2020.09.08 14:27:23 EEST
Reason: MoldSign Signature
Location: Moldova

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-20-687

Concerned medical devices;

Product	Model	Model Number
Intraocular Lenses	ACRIVA UD 613	M003G
	ACRIVA UDB625	M004G
	ACRIVA UDC625	M014G
	ACRIVA HAF	M021G
	ACRIVA UDM 611	M012G
	ACRIVA REVIOL MF 613	M016G
	ACRIVA REVIOL MFB 625	M018G
	ACRIVA REVIOL MFM 611	M017G
	ACRIVA OCEAN SVT 100	M069G
	ACRIVA OCEAN T SVT 200	M070G
	ACRIVA ADVANTAGE C	M079G
	ACRIVA ADVANTAGE C TORIC	M080G
	ACRIVA ADVANTAGE	M081G
	ACRIVA ADVANTAGE TORIC	M082G
	OCUVA A625	M002G
	OCUVA 625	M022G
	OCUVA AB625	M027G
	ACRIVA BB UD 613	M025G
	ACRIVA BB UDM611	M031G
	ACRIVA REVIOL BB MF613	M033G
	ACRIVA REVIOL BB MFM611	M032G
	ACRIVA BB T UDM 611	M029G
	ACRIVA REVIOL BB T MFM 611	M030G
	ACRIVA TRINOVA PRO	M0220G
	ACRIVA TRINOVA PRO TORIC	M0221G
	ACRIVA TRIVISION	M096G
	ACRIVA TRIVISION TORIC	M097G
	ACRIVA TRINOVA PRO C	M077G
	ACRIVA TRINOVA PRO C TORIC	M083G
	ENOVA GF3	M055G
	ENOVA T GF3	M085G
	ENOVA CL	M086G
	ENOVA T CL	M087G
	ENOVA GF1	M058G
	ENOVA T GF1	M084G
	ENOVA ADC	M088G
	ENOVA T ADC	M089G

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24 July 2020, Istanbul, Turkey

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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-20-687

Concerned medical devices;

Product	Model	Model Number
Intraocular Lenses	ENOVA ADCL	M090G
	ENOVA T ADCL	M0100G
	ENOVA AD	M0101G
	ENOVA T AD	M0102G
	ENOVA TRIVISION C	M0103G
	ENOVA TRIVISION T C	M0104G
	ENOVA TRIVISION CL	M0105G
	ENOVA TRIVISION T CL	M0106G
	ENOVA TRIVISION	M0107G
	ENOVA TRIVISION T	M0108G
	ENOVA MAESTRO C	M0109G
	ENOVA MAESTRO T C	M0110G
	ENOVA MAESTRO CL	M0111G
	ENOVA MAESTRO T CL	M0112G
	ENOVA MAESTRO	M0113G
	ENOVA MAESTRO T	M0114G
Intraocular Lenses (Preloaded)	ENOVA PGF3	M059G
	ENOVA T PGF3	M0115G
	ENOVA CLP	M0116G
	ENOVA T CLP	M0117G
	ENOVA PGF1	M060G
	ENOVA T PGF1	M0118G
	ENOVA PADC	M0119G
	ENOVA T PADC	M0120G
	ENOVA PADCL	M0121G
	ENOVA T PADCL	M0122G
	ENOVA PAD	M0123G
	ENOVA T PAD	M0124G
	ENOVA TRIVISION CP	M0125G
	ENOVA TRIVISION T CP	M0126G
	ENOVA TRIVISION CLP	M0127G
	ENOVA TRIVISION T CLP	M0128G
	ENOVA TRIVISION P	M0129G
	ENOVA TRIVISION TP	M0130G
	ENOVA MAESTRO CP	M0131G
	ENOVA MAESTRO T CP	M0132G

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Head of Notified Body

24 July 2020, Istanbul, Turkey

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CERTIFICATE

kiwa

Enclosure of the EC Certificate:

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

Certificate Number: 1984-MDD-20-687

Concerned medical devices;

Product	Model	Model Number
Intraocular Lenses (Preloaded)	ENOVA MAESTRO CLP	M0133G
	ENOVA MAESTRO T CLP	M0134G
	ENOVA MAESTRO P	M0135G
	ENOVA MAESTRO TP	M0136G
Ophthalmic Viscosurgical Medical Devices	PROTECTALON 1.0 %	MV006G
	PROTECTALON 1.2 %	MV007G
	PROTECTALON 1.4 %	MV001G
	PROTECTALON 1.6%	MV008G
	PROTECTALON 1.8 %	MV002G
	PROTECTALON 2.0 %	MV003G
	CAPSULVISC 2.0 %	MV064G
	PROTECTALON 3.0%	MV004G
	CAPSULVISC 3.0 %	MV065G
	PROTECTACEL 2.0%	MV005G
	CAPSULGEL 2.0 %	MV063G
	PROTECTALON DUO	MV114G
Cartridge & Injector for Ophthalmology	ACRIJET GREEN 1.8	ME016G,ME021G
	ACRIJET FLY 1.8	ME034G , ME044G
	ACRIJET GREEN 2.0	ME017G,ME022G
	ACRIJET FLY 2.0	ME035G , ME045G
	ACRIJET GREEN 2.2	ME018G,ME023G
	ACRIJET FLY 2.2	ME036G , ME046G
	ACRIJET GREEN 2.4	ME019G,ME024G
	ACRIJET FLY 2.4	ME037G , ME047G
Intraarticular Viscosupplementation Medical Devices	REVISCON 1.0%	MV015G
	EVISC 1.0%	MV052G
	REVISCON PLUS 1.6%	MV016G
	ROMOVA PLUS 1.6 %	MV072G
	EVISC PLUS 1.6%	MV053G
	REVISCON MONO 2.0 %	MV044G
	EVISC MORE 2.0 %	MV076G

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Certificate Number: 1984-MDD-20-687

Concerned medical devices;

Product	Model	Model Number
Intraarticular Viscosupplementation Medical Devices	DREAMVISC 1.0%	MV105G
	DREAMVISC 1.6%	MV106G
	DREAMVISC 2.0%	MV107G
	TRUVISC 1.0%	MV119G
	TRUVISC 1.6%	MV120G
	TRUVISC 2.0%	MV121G
	VISCART 1.0%	MV122G
	VISCART 1.6%	MV123G
	VISCART 2.0%	MV124G
	SAFEVISC 1.0%	MV116G
	SAFEVISC 1.6%	MV117G
	SAFEVISC 2.0%	MV118G
	HAVISC 1.0%	MV111G
	HAVISC 1.6%	MV112G
	HAVISC 2.0%	MV113G

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

24 July 2020, Istanbul, Turkey

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