CERTIFICATE

EC Certificate

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

Certificate Number: 1984-MDD-18-490

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 B.V.

Strawinskylaan 1143, 1077 XX Amsterdam, The Netherlands

Products: Intraocular Lenses, Ophthalmic Viscosurgical Medical Devices, Intraarticular Viscosupplementation Medical Devices, Cartridge & Injector System

The products defined at the enclosure which is the part of this certificate and contains two (2) 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.4302.06
Date of first issue: 01 February 2018
Date of last issue: 10 June 2020
Revision Number: 04
Expiry Date: 27 May 2024

Muhteşem Gökhan Yücel
Head of Notified Body

10 June 2020, Istanbul, Turkey

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

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-18-490, Revision Number: 04

Concerned medical devices;

Product	Model	Reference Number
Intraocular Lenses	ACRIVA OCEAN SVT 100	M069H
	ACRIVA OCEAN T SVT 200	M070H
	ACRIVA TRINOVA	M071H
	ACRIVA REVIOL TRI-ED+611	M051H
	ACRIVA REVIOL TRI-ED+T611	M065H
	ACRIVA TRINOVA TORIC	M072H
	ACRIVA TRIVISION	M096H
	ACRIVA TRIVISION TORIC	M097H
	ENOVA GF1	M058H
	ENOVA GF3	M055H
	ACRIVA UD 613	M003H
	ACRIVA UDB625	M004H
	ACRIVA UDC625	M014H
	ACRIVA HAF	M021H
	ACRIVA UDM 611	M012H
	ACRIVA REVIOL MF 613	M016H
	ACRIVA REVIOL MFB 625	M018H
	ACRIVA REVIOL MFM 611	M017H
	OCUVA A625	M002H
	OCUVA 625	M022H
	OCUVA AB625	M027H
	ACRIVA BB UD 613	M025H
	ACRIVA BB UDM611	M031H
	ACRIVA REVIOL BB MF613	M033H
	ACRIVA BB T UDM 611	M029H
	ACRIVA REVIOL BB MFM611	M032H
	ACRIVA REVIOL BB T MFM611	M030H
Ophthalmic Viscosurgical Medical Devices	PROTECTALON 3.0%	MV004H
	CAPSULVISC 3.0 %	MV065H
	CAPSULVISC 2.0 %	MV064H
	PROTECTACEL 2.0%	MV005H
	CAPSULGEL 2.0 %	MV063H
	PROTECTALON 1.0%	MV006H
	PROTECTALON 1.2 %	MV007H
	PROTECTALON 1.4 %	MV001H
	PROTECTALON 1.6%	MV008H
	PROTECTALON 1.8 %	MV002H
	PROTECTALON 2.0 %	MV003H

10 June 2020, Istanbul, Turkey

Muhteşem Gökhan Yücel
Head of Notified Body

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

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-18-490, Revision Number: 04

Concerned medical devices;

Product	Model	Reference Number
Intraarticular Viscosupplementation Medical Devices	EVISC 1.0%	MV059
	EVISC PLUS 1.6%	MV060
	REVISCON MONO 2.0 %	MV044
	EVISC MORE 2.0 %	MV061
	REVISCON 1.0%	MV015H
	REVISCON PLUS 1.6%	MV016H
	ROMOVA PLUS 1.6 %	MV067, MV019
Cartridge & Injector System	ACRIJET GREEN 1.8	ME021H, ME016H
	ACRIJET GREEN 2.0	ME022H, ME017H
	ACRIJET GREEN 2.2	ME023H, ME018H
	ACRIJET GREEN 2.4	ME024H, ME019H

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

10 June 2020, Istanbul, Turkey

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