VSY BIOTECHNOLOGY

VSY Biotechnology BV
Strawinskylaan 1143 1077 XX
Amsterdam-The Netherlands
info@vsybiotechnology.com
www.vsybiotechnology.com

DECLARATION OF CONFORMITY

We

Name and Adress of Manufacturer **VSY Biotechnology BV**
Strawinskylaan 1143 1077XX Amsterdam The Netherlands

declare on our own responsibility that the medical device

Name of Medical Device: **Intraocular Lens**

Model	Reference Number
ACRIVA OCEAN SVT 100	M069H
ACRIVA OCEAN T SVT 200	M070H
ACRIVA TRINOVA	MO71H
ACRIVA REVIOL TRI-ED+611	M051H
ACRIVA REVIOL TRI-ED+ T 611	M065H
ACRIVA TRINOVA TORIC	M072H
ACRIVA TRIVISION	M096H
ACRIVA TRIVISION TORIC	M097H
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 A 625	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

GMDN-Code: **35658**

Duration of validity: (see below)

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Class: **IIb** (According to annex IX of directive 93/42/EEC)

Meets all applicable requirements of the Directive 93/42/EEC

Standards: ISO 13485, ISO 10993-1, ISO 11979-1, ISO 11979-2, ISO 11979-3, ISO 11979-4, ISO 11979-5, ISO 11979-6, ISO 11979-7, ISO 11979-8, ISO 11979-9, ISO 15223-1, ISO 14971, ISO 17665-1, EN 62366

Name, Address and Identification **Kiwa Certification Serivces Inc.**
ITOSB:9 Cadde No:15 Tepeören Tuzla, Istanbul, Turkey,

Number of Notified Body: **1984**

Conformity Assessment Procedure: **93/42/EEC, Annex II (excluding 4)**

CE Certificate Number: **1984-MDD-18-490**

Validity: 27.05.2024

Amsterdam, 06.01.2021
Place, Date

Director
Dr. Ercan VARLIBAŞ

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