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REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF FINANCE
BUREAU OF CUSTOMS
MANILA 1099

June 20, 2016

CUSTOMS MEMORANDUM CIRCULAR
NO. 85-2014

TO: All Deputy Commissioners
All Directors and Division Chiefs
All District / Port Collectors
and Others Concerned

SUBJECT: Updated List of Valid Registered Intraocular Lens as of June 15, 2016

Attached is the letter of Engr. Bayani C. San Juan, Officer-in-Charge, Center for Device Regulation, Radiation Health, and Research (CDRRHR), FDA-DOH, endorsing the updated list of intraocular lenses with a Certificate of Product Registration as of 15 June 2016.

DOH-FDA-CDRRHR is requesting that only the Intra-ocular lenses with Certificate of Product Registration are released by this Bureau.

For your information and guidance.

Please confirm the dissemination of this circular throughout your offices within fifteen (15) days from receipt hereof.


ALBERTO D. LINA
Commissioner



JUN 21 2016

CMC 85-2010 P-2

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Republic of the Philippines
Department of Health
Food and Drug Administration

CENTER FOR DEVICE REGULATION, RADIATION HEALTH, AND RESEARCH
(former name : Bureau of Health Devices and Technology)



16 June 2016

ATTY. ALBERTO D. LINA
Commissioner
Bureau of Customs
G/F, OCOM Bldg., Port Area, Manila

Dear Commissioner Lina:

This refers to the use of unregistered intraocular lens.

We seek your assistance to ensure that only the Intra-ocular lenses with a Certificate of Product Registration issued by our office are released by the Bureau of Customs.

Attached is the updated list of intraocular lenses with a Certificate of Product Registration as of 15 June 2016

Thank you.

Very truly yours,

ENGR. BAYANI C. SAN JUAN, MSc, MNSA
Officer-in-Charge



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FOOD AND DRUG ADMINISTRATION
Center for Device Regulation, Radiation Health, and Research
List of Valid Registered Intraocular Lens as of June 15, 2016

Importer / Distributor / Trader	Product	Model/ Reference Codes	Product Registration Number	Validity	Manufacturer
Alcon Laboratories (Phils), Inc.	Intraocular Lens - PMMA	MTA3UO, MTA4UO, MTA5UO	DVR-2553	30-Jan-21	Alcon Laboratories, Inc. - Texas, USA mfd. by: Alcon Research, Ltd. - West Virginia, USA
Alcon Laboratories (Phils), Inc.	Intraocular Lens - PMMA	MZ30BD, MZ40BD, MZ50BD, MZ60BD	DVR-2560	30-Jan-21	Alcon Laboratories, Inc. - Texas, USA mfd. by: Alcon Research, Ltd. - West Virginia, USA
Alcon Laboratories (Phils), Inc.	Acrysof Intraocular Lens - Acrylic	MA30BA, MA60MA, MA60BM, SA60AT	DVR-2929	30-Jan-21	Alcon Laboratories, Inc. - Texas, USA mfd. by: Alcon Research, Ltd. - West Virginia, USA
I-Senz Medical Inc.	Neo Eye Intraocular Lens	RP II (RE 03PH)	DVR-3300	09-Aug-18	PT Rohto Laboratories Indonesia - Indonesia
Alcon Laboratories (Phils), Inc.	Acrysof Natural Single Piece Intraocular Lens	SN60AT	DVR-5046	13-May-20	Alcon Laboratories, Inc. - Texas, USA mfd. by: Alcon Laboratories, Inc. - Forth Worth, Texas, USA
I-Senz Medical Inc.	Neo-Eye Foldable Lens	RF 22L	DVR-5134	14-Oct-18	PT Rohto Laboratories Indonesia - Indonesia
Alcon Laboratories (Phils), Inc.	Acrysof Natural Single Piece Intraocular Lens	SN60WF	DVR-5965	10-Feb-21	Alcon Laboratories, Inc. - Texas, USA mfd. by: Alcon Research, Ltd. - West Virginia, USA
Bausch & Lomb Philippines Inc.	Akreos Adapt Intraocular Lens	no model available	DVR-6138	28-Aug-18	Bausch & Lomb, Inc. - New York, USA mfd. by: Bausch & Lomb Chauvin Opsia - Cedex, France
Brady Pharma Inc.	Aurolens Single Piece Intraocular Lens	S3500, S3525, S3P550L, S3P602, SN3550EL, S3642, SC6530, B1602, B3602, A5028, A5528, A5520, A5525, S3602, S3600L, S3602L, S3550, A5530	DVR-6272	27-Oct-18	Aurolab - India

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Brady Pharma Inc.	Aurofold Hydrophilic Foldable Intraocular Lens	FH3575	DVR-6275	27-Oct-18	Aurolab - India
Integrated Ophthalmic Products, Inc.	Sensar Foldable Intraocular Lens with Optiedge	AR40E, ARO4E, AR40M	DVR-6373	17-Jan-18	Abbott Medical Optics Inc. - Dublin, Ireland mfd. By: AMO Puerto Rico Manufacturing, Inc. - PR, USA
Integrated Ophthalmic Products, Inc.	Tecnis Foldable Acrylic Intraocular Lens	ZA9003	DVR-6374	17-Jan-18	Abbott Medical Optics Inc. - Dublin, Ireland mfd. By: AMO Puerto Rico Manufacturing, Inc. - PR, USA
Alcon Laboratories (Phils), Inc.	Acrysof Toric Single Piece Acrylic Intraocular Lens	SN60T3, SN60T4, SN60T5, SN60T6, SN60T7, SN60T8, SN60T9	DVR-6520	06-Mar-19	Alcon Laboratories, Inc. - Texas, USA mfd. by: Alcon Research, Ltd. - West Virginia, USA
Bausch & Lomb Philippines Inc.	Akreos Adapt AO (Advanced Optics Aspheric Lens) Intraocular Lens	no model available	DVR-6536	27-Mar-19	Bausch & Lomb, Inc. - New York, USA mfd. by: Bausch & Lomb Chauvin Opsia - Cedex, France
Alcon Laboratories (Phils), Inc.	Acrysof Intraocular Lens	MA30Ac	DVR-7383	18-Jun-19	Alcon Laboratories, Inc. - Texas, USA mfd. by: Alcon Research, Ltd. - West Virginia, USA

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Alcon Laboratories (Phils), Inc.	Acrysoft Restor Apodized Diffractive Aspheric Intraocular Lens	SN6AD1	DVR-7436	29-Jul-19	Alcon Laboratories, Inc. - Texas, USA mfd. by: Alcon Research, Ltd. - West Virginia, USA
Hollywood Vision Care Center	Ocuflex Foldable Intraocular Lens	ANU6	DVR-7691	12-Sep-16	Polymer Technologies International - India
Bausch & Lomb Philippines Inc.	Crystalens Accomodating Intraocular Lens	AT52SE, HD500, AT50A0, AT52A0	DVR-7764	14-Apr-20	Bausch & Lomb, Inc. - New York, USA mfd. by: Bausch & Lomb - Cucamonga, CA, USA
Alcon Laboratories (Phils), Inc.	Acrysof IQ Toric Astigmatism Intraocular Lens	SN6AT2, SN6AT3, SN6AT4, SN6AT5, SN6AT6, SN6AT7, SN6AT8, SN6AT9	DVR-7917	31-Jul-20	Alcon Laboratories, Inc. - Forth Worth, Texas, USA mfd by: Alcon Research, Ltd - USA
Alcon Laboratories (Phils), Inc.	Acrysof IOL Sterile UV-Absorbing Acrylic Foldable Multipiece Posterior Chamber Lenses	MA60AC	DVR-7920	31-Jul-20	Alcon Laboratories, Inc. - USA mfd by: Alcon Research, Ltd - WV, USA
I-Senz Medical Inc.	Aspira Acrylic Intraocular Lens	Aspira-aAY	DVR-7952	24-Aug-20	Human Optics - Erlangen, Germany
I-Senz Medical Inc.	Hoya-PS AF-1 (UY) Hoya Preloaded System Intraocular Lens	PY-60AD	DVR-8425	25-Jun-16	Hoya Medical Singapore Pte. Ltd. - Singapore

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Importer / Distributor / Trader	Product	Model/ Reference Codes	Product Registration Number	Validity	Manufacturer
Alcon Laboratories (Phils.) Inc.	Acrysof IQ Restor Multifocal Toric Intraocular Lens	SND1T2, SND1T3, SND1T4, SND1T5	DVR-8554	22-Sep-18	Alcon Laboratories, Inc. - USA mfd. By: Alcon Research, Ltd. - WV, USA
Alcon Laboratories (Phils.) Inc.	Acrysof IQ Restor Intraocular Lens	MD6AD1	DVR-8569	28-Sep-18	Alcon Laboratories, Inc. - USA mfd. By: Alcon Research Ltd. - WV, USA
Alcon Laboratories (Phils.) Inc.	Acrysof IQ Intraocular Lens with the Acrysert Delivery System	SN6CWS	DVR-8597	09-Oct-18	Alcon Laboratories, Inc. - USA mfd. By: Alcon Research Ltd. - WV, USA
Integrated Ophthalmic Products, Inc.	Tecnis Multifocal Intraocular Lens	ZMBOO	DVR-8711	07-Feb-19	Abbott Medical Optics Inc. - Dublin, Ireland mfd. By: AMO Groningen B.V. - Groningen, The Netherlands
Integrated Ophthalmic Products, Inc.	Technis 1-Piece Acrylic Aspheric Intraocular Lens	ZCBOO	DVR-8712	07-Feb-19	Abbott Medical Optics Inc. - Dublin, Ireland mfd. By: AMO Puerto Rico Manufacturing, Inc. - PR, USA
Micro-Biological Laboratory Inc.	AT Lisa 809 Acrylic Intraocular Lens	no model available	DVR-8839	01-Apr-18	Carl Zeiss Meditec AG - Jena Germany
Micro-Biological Laboratory Inc.	AT Torbi 709M Acrylic Intraocular Lens	no model available	DVR-8840	01-Apr-18	Carl Zeiss Meditec AG - Jena Germany
Micro-Biological Laboratory Inc.	AT Lisa 909M Toric Acrylic Intraocular Lens	no model available	DVR-8841	01-Apr-18	Carl Zeiss Meditec AG - Jena Germany

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Micro-Biological Laboratory Inc.	CT Asphina 509M Acrylic Intraocular Lens	no model available	DVR-8864	07-Apr-18	Carl Zeiss Meditec AG - Jena Germany
I-Senz Medical Inc.	Texel Soft Hydrophilic Acrylic Intraocular Lens	EF-900	MDR-00073	22-Jul-18	Eagle Optics Pvt. Ltd. - India
Alcon Laboratories	Acrysof Natural Single Piece Intraocular Lens (UV with Blue Light Filter)	SN60AT	MDR-00083	27-Jul-18	Alcon Laboratories Ireland Ltd. - Ireland
Alcon Laboratories	Acrysof Acrylic Foldable Single-Piece Intraocular Lens	SA60AT	MDR-00084	27-Jul-18	Alcon Laboratories Ireland Ltd. - Ireland
Alcon Laboratories	Acrysof IQ Aspheric Natural Single-Piece Intraocular Lens	SN60WF	MDR-00087	28-Jul-18	Alcon Laboratories Ireland Ltd. - Ireland
I-Senz Medical Inc.	Texel PMMA Intraocular Lens	ES-101, ES-109, ES-102, ES-105, ES-106, ES-204	MDR-00138	08-Sep-18	Eagle Optics Pvt. Ltd. - India
I-Senz Medical Inc.	DiffRACTIVA Intraocular Lens (Acrylic)	Diff-aAY	MDR-00143	23-Sep-18	Human Optics AG - Germany
Alcon Laboratories	Acrysof IQ Restor Apodized Diffractive Aspheric Multifocal Intraocular Lens	SN6AD1	MDR-00163	04-Oct-18	Alcon Laboratories, Inc. - USA mfd. by: Alcon Laboratories Ireland Ltd. - Ireland

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Alcon Laboratories	Monarch II Intraocular Lens Delivery System P Cartridge	8065977768	MDR-00248	16-Nov-18	Alcon Laboratories, Inc. - USA mfd. By: Alcon Research, Ltd. - WV, USA
Alcon Laboratories	Monarch II Intraocular Lens Delivery System B and C Cartridges	8065977758, 8065977759	MDR-00249	16-Nov-18	Alcon Laboratories, Inc. - USA mfd. By: Alcon Research, Ltd. - WV, USA
Brady Pharma Inc.	Aurolens PMMA IOL	S3602R, S3500R	MDR-00286	12-Dec-18	Aurolab - India
Alcon Laboratories	Monarch III Intraocular Lens Delivery System	8065977763, 8065977762	MDR-00293	21-Dec-18	Alcon Laboratories, Inc. - USA mfd. By: Alcon Research, Ltd. - WV, USA
Brady Pharma Inc.	Softec HD Bi-Aspheric Intraocular Lens	no model available	MDR-00308	16-Jan-19	Lenstec (Barbados) Inc. - Barbados
Brady Pharma Inc.	Tetraflex Presbyopic Intraocular Lens	no model available	MDR-00321	24-Jan-19	Lenstec (Barbados) Inc. - Barbados
Brady Pharma Inc.	Softec I Intraocular Lens	93751684	MDR-00464	26-Mar-19	Lenstec (Barbados) Inc. - Barbados
Croma Medic, Inc.	Mediphacos Ioflex Intraocular Lens	24096	MDR-00542	16-Apr-18	Mediphacos Ltda. - Brazil
Filipinas Teknomed Marketing Corporation	Appalens Intra-Ocular Lens	100, 101, 302	MDR-00568	20-Apr-19	Appasamy Associates - Chennai, India mfd. By: Appasamy Ocular Devices (P) Limited - Puducherry, India
I-Senz Medical Inc.	Hoya Isert Preloaded IOL Posterior Chamber Type	iSert 251	MDR-00591	07-May-18	Hoya Medical Singapore Pte. Ltd. - Singapore

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Filipinas Teknomed Marketing Corporation	Ezy Fold Intra-Ocular Lens	502	MDR-00660	19-Jun-18	Appasamy Associates - Chennai, India mfd. By: Appasamy Ocular Devices (P) Limited - Puducherry, India
Brady Pharma Inc.	Tetraflex HD Active Lifestyle Intraocular Lens	no model available	MDR-00781	15-Aug-18	Lenstec (Barbados) Inc. - Barbados
Hollywood Vision Care Center	Spectra PMMA Single Piece Intraocular Lens	S613, PH5	MDR-00910	19-Oct-18	Spectra Vision - India
Brady Pharma Inc.	Auroflex Hydrophilic Foldable Poly Hydroxy Ethyl Methacrylate with Dual Haptic Intraocular Lens	FH5600SQ/C200-DI100	MDR-00961	04-Dec-18	Aurolab - India
Filipinas Teknomed Marketing Corporation	Supra Phob Ophthalmic Foldable Intraocular Lens	SPNT200	MDR-00970	05-Dec-18	Appasamy Associates - Chennai, India mfd. By: Appasamy Ocular Devices (P) Limited - Puducherry, India
Medilight Incorporated	Rayner C-Flex Hydrophilic Acrylic Injectable Intraocular Lens with Enhanced Square Edge	570C	MDR-00972	07-Dec-18	Rayner International Lenses Limited - Chesham, Bucks, England mfd. by: Rayner Intraocular Lenses Limited - East Sussex, England
Filipinas Teknomed Marketing Corporation	Acryfold Foldable Ophthalmic Intraocular Lens	601	MDR-01121	08-Mar-19	Appasamy Associates - Chennai, India mfd. By: Appasamy Ocular Devices (P) Limited - Puducherry, India

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Alcon Laboratories (Phils.) Inc.	Acrysof IQ Restor Single Piece Acrylic Foldable Lens, UV with Blue Light Filter, Apodized Diffractive Aspheric Optic, Multifocal Intraocular Lens	SV25T0	MDR-01128	08-Mar-19	Alcon Laboratories, Inc. - Texas, USA mfd. by: Alcon Research, Ltd. - West Virginia, USA
Brady Pharma Inc.	Aurolens Three Piece Intraocular Lens	B3602	MDR-01148	02-Apr-19	Aurolab - India
Alcon Laboratories (Phils.) Inc.	Acrysof IQ Restor Multifocal Toric Intraocular Lens, UV with Blue Light Filter	SV25T2, SV25T3, SV25T4, SV25T5	MDR-01214	07-May-19	Alcon Laboratories Inc. - Texas, USA mfd. by: Alcon Research Ltd. - West Virginia, USA
(FMEI) - Fernando Medical Enterprises, Inc.	Duralens II Intraocular Lens	53 (7207121010)	MDR-01233	07-May-19	Abbott Medical Optics Inc. - USA mfd. by: Aaren Scientific Inc. - USA
Filipinas Teknomed Marketing Corporation	Appalens Intraocular Lens	207	MDR-01326	17-Jul-19	Appasamy Associates & Group of Companies - India mfd. by: Appasamy Ocular Devices (P) Ltd. - India
Bausch & Lomb Philippines Inc.	En Vista Hydrophobic Acrylic Intraocular Lens	MX60	MDR-01409	30-Jul-19	Bausch & Lomb, Inc. - New York, USA mfd. by: Bausch & Lomb - Clearwater, Florida, USA

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Importer / Distributor / Trader	Product	Model/ Reference Codes	Product Registration Number	Validity	Manufacturer
Filipinas Teknomed Marketing Corporation	nAspro-BBY (Blue Blocking Yellow) Aspheric Foldable Posterior Chamber Intraocular Lens	nAsY207	MDR-01587	29-Oct-19	Appasamy Associates - Chennai, India mfd. By: Appasamy Ocular Devices (P) Limited - Puducherry, India
LSGI Corporation	Bi Flex Aspheric Hydrophilic Acrylic Foldable Intraocular Lens, Sterile	677ABY (YELLOW)	MDR-02542	19-Dec-20	Medicontour Medical Engineering Ltd. - Hungary
LSGI Corporation	Bi Flex Aspheric Hydrophilic Acrylic Foldable Intraocular Lens, Sterile	677AB (CLEAR)	MDR-02544	19-Dec-20	Medicontour Medical Engineering Ltd. - Hungary
Bausch & Lomb Philippines Inc.	Envista Toric Hydrophobic Acrylic Intraocular Lens	MX60T	MDR-02860	03-Mar-21	Bausch & Lomb Inc. - New York, USA mfd. By: Bausch & Lomb - Clearwater, Florida, USA
Bausch & Lomb Philippines Inc.	Bausch & Lomb IOL Injector	INJ100	MDR-03046	05-May-21	Bausch & Lomb Inc. - New York, USA mfd. By: Medice AG - Wolfhaden, Switzerland
Alcon Laboratories (Phils.) Inc.	Acrysof IQ Toric Astigmatism Intraocular Lens, Sterile UV and Light Filtering Acrylic Foldable Toric Aspheric Optic, Single-Piece Posterior Chamber Lens	SN6AT2, SN6AT3, SN6AT4, SN6AT5	MDR-03091	12-May-21	Alcon Laboratories Inc. - Texas, USA mfd. By: Alcon Laboratories Ireland, Ltd. - Cork, Ireland

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Importer / Distributor / Trader	Product	Model/ Reference Codes	Product Registration Number	Validity	Manufacturer
Filipinas Teknomed Marketing Corporation	Supra Phob BBY Ophthalmic Intra-Ocular Lens, Blue Blocking Yellow, Hydrophobic Foldable Intraocular Lens with Aspheric Optics	Supra Phob-BBY	MDR-03253	06-Jul-21	Appasamy Associates - Chennai, India mfd. By: Appasamy Ocular Devices (P) Limited - Puducherry, India
Brady Pharma, Inc.	Truedge PMMA Intraocular Lens with Square Edge	S362SQAS	MDR-03354	10-Aug-16	Aurolab - Tamil Nadu, India
Micro-Biological Laboratory, Inc. Doing Business under Name Microlab	AT Lisa Toric 909 MP Preloaded Intraocular Lens	no model available	MDR-03391	17-Aug-16	Carl Zeus Meditec AG - Berlin, Germany mfd. By: Carl Zeus Meditec AG - Jena, Germany
Micro-Biological Laboratory, Inc. Doing Business under Name Microlab	AT Torbi 709 MP Preloaded Intraocular Lens	1S1303190032	MDR-03392	17-Aug-16	Carl Zeus Meditec AG - Berlin, Germany mfd. By: Carl Zeus Meditec AG - Jena, Germany
Micro-Biological Laboratory, Inc. Doing Business under Name Microlab	AT Lisa 809 MP Preloaded Intraocular Lens	no model available	MDR-03393	17-Aug-16	Carl Zeus Meditec AG - Berlin, Germany mfd. By: Carl Zeus Meditec AG - Jena, Germany