



EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. CE 637897
Issued To: **AST Products, Inc.**
9 Linnell Circle
Billerica
Massachusetts
01821
USA

In respect of:

Design and manufacture of sterile soft hydrophobic acrylic monofocal, monofocal toric, extended depth of focus, extended depth of focus toric, multifocal, multifocal toric, trifocal and trifocal toric intraocular lenses, and corresponding sterile preloaded lens delivery systems, and sterile intraocular lens guides.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2015-09-07**

Date: **2021-04-12**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

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Supplementary Information to CE 637897

Issued To: **AST Products, Inc.
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Number	Device Name	Intended Purpose per IFU
Class IIb		
35658	Posterior-chamber monofocal intraocular lens, pseudophakic	For visual correction of aphakia in adult patients following successful cataractous lens extraction.
35658	Posterior-chamber toric intraocular lens, pseudophakic	For Visual correction of aphakia and pre-existing corneal astigmatism in adult patients with or without presbyopia, who desire improved uncorrected distance vision, reduction of residual refractive cylinder, and increased spectacle independence for distance vision following removal of a cataractous lens.
35658	Posterior-chamber extended depth of focus intraocular lens, pseudophakic	For the visual correction of aphakia in adult patients following successful cataractous lens extraction who desire improved intermediate and near visual acuity, while maintaining comparable distance visual acuity.
35658	Posterior-chamber multifocal intraocular lens, pseudophakic	For the visual correction of aphakia in adult patients with or without presbyopia, who desire near, intermediate, and distance vision with increased spectacle independence following removal of a cataractous lens.

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Number	Device Name	Intended Purpose per IFU
Class IIb		
35658	Posterior-chamber trifocal intraocular lens, pseudophakic	For the visual correction of aphakia in adult patients with or without presbyopia, who desire near, intermediate, and distance vision with increased spectacle independence following removal of a cataractous lens.
35658	Preloaded Monofocal Intraocular Lens Delivery Systems	For the placement of a foldable monofocal intraocular lens that is intended for visual correction of aphakia following successful cataractous lens extraction.
35658	Preloaded Monofocal Toric Intraocular Lens Delivery Systems	For the placement of a foldable toric intraocular lens that is intended for visual correction of aphakia and pre-existing corneal astigmatism in adult patients with or without presbyopia, who desire improved uncorrected distance vision, reduction of residual refractive cylinder, and increased spectacle independence for distance vision following successful cataractous lens extraction.
35658	Preloaded Extended Depth of Focus Intraocular Lens Delivery Systems	For the placement of a foldable EDOF intraocular lens that is intended for visual correction of aphakia in adult patients who desire improved intermediate and near visual acuity, while maintaining comparable distance visual acuity following successful cataractous lens extraction.

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Number	Device Name	Intended Purpose per IFU
Class IIb		
35658	Preloaded Multifocal Intraocular Lens Delivery Systems	For the placement of a foldable multifocal intraocular lens that is intended for visual correction of aphakia in adult patients with or without presbyopia, who desire near, intermediate, and distance vision with increased spectacle independence following successful cataractous lens extraction.
35658	Preloaded Trifocal Intraocular Lens Delivery Systems	For the placement of a foldable trifocal intraocular lens that is intended for visual correction of aphakia in adult patients with or without presbyopia, who desire near, intermediate, and distance vision with increased spectacle independence following successful cataractous lens extraction.
35658	Posterior-chamber EDOF Toric intraocular lens, pseudophakic	Indicated for primary implantation for the visual correction of aphakia and for reduction of residual refractive astigmatism in adult patients in whom a cataractous lens has been removed. The lens provides improved intermediate and near visual acuity, while maintaining comparable distance visual acuity.

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Number	Device Name	Intended Purpose per IFU
Class IIb		
35658	Posterior-chamber Multifocal Toric intraocular lens, pseudophakic	Indicated for the replacement of the human lens to achieve visual correction of aphakia and for reduction of residual refractive astigmatism in adult patients with and without presbyopia in whom a cataractous lens has been removed by phacoemulsification and who desire near, intermediate, and distance vision with increased spectacle independence.
35658	Posterior-chamber Trifocal Toric intraocular lens, pseudophakic	Indicated for the replacement of the human lens to achieve visual correction of aphakia and for reduction of residual refractive astigmatism in adult patients with and without presbyopia in whom a cataractous lens has been removed by phacoemulsification and who desire near, intermediate, and distance vision with increased spectacle independence.

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Number	Device Name	Intended Purpose per IFU
Class IIb		
35658	Preloaded Extended Depth of Focus Toric Intraocular lens delivery Systems	For the placement of a foldable EDOF Toric intraocular lens that is intended for the visual correction of aphakia and for reduction of residual refractive astigmatism in adult patients in whom a cataractous lens has been removed. The lens provides improved intermediate and near visual acuity, while maintaining comparable distance visual acuity.
35658	Preloaded Multifocal Toric Intraocular Lens Delivery System	For the placement of a foldable Multifocal Toric intraocular lens that is intended for the replacement of the human lens to achieve visual correction of aphakia and for reduction of residual refractive astigmatism in adult patients with and without presbyopia in whom a cataractous lens has been removed by phacoemulsification and who desire near, intermediate, and distance vision with increased spectacle independence.

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Number	Device Name	Intended Purpose per IFU
Class IIb		
35658	Preloaded Trifocal Toric Intraocular Lens Delivery System	For the placement of a foldable Trifocal Toric intraocular lens that is intended for the replacement of the human lens to achieve visual correction of aphakia and for reduction of residual refractive astigmatism in adult patients with and without presbyopia in whom a cataractous lens has been removed by phacoemulsification and who desire near, intermediate, and distance vision with increased spectacle independence.

Number	Device Name	Intended Purpose per IFU
Class IIa		
MD0105	Manual intraocular lens injector, single-use	N/A

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