

Device Schedule:

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Intended purpose (as per the IFU)	Risk Classification	Basic UDI-DI
Marketing name: PODEYE Commercial name: PODEYE Technical name: PODAGF Aphakic, Monofocal, Aspherical, Hydrophobic Acrylic Intraocular Lens	PODEYE	MDN 1104	The posterior chamber intraocular lens is intended to be placed into the capsular bag with an anterior capsulorhexis for the replacement of the human lens to achieve the visual correction of aphakia in adult patients in whom the cataractous lens has been removed. The lens is indicated for adult patients, surgically treated for cataract, who desire improved uncorrected far vision.	Class Iib, Implantable	0541484601001006V

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Intended purpose (as per the IFU)	Risk Classification	Basic UDI-DI
<p>Marketing name: PODEYE TORIC</p> <p>Commercial name: PODEYE TORIC</p> <p>Technical name: PODT49P</p> <p>Aphakic, Monofocal, Toric, Hydrophobic Acrylic Intraocular Lens</p>	<p>PODEYE TORIC</p>	<p>MDN 1104</p>	<p>The posterior chamber intraocular lens is intended to be placed into the capsular bag with an anterior capsulorhexis for the replacement of the human lens to achieve the visual correction of aphakia in adult patients in whom the cataractous lens has been removed.</p> <p>The lens is indicated for adult patients, with pre-existing astigmatism, surgically treated for cataract, who desire improved uncorrected far vision, with reduced spectacle dependence.</p>	<p>Class IIb, Implantable</p>	<p>0541484601001006V</p>

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Intended purpose (as per the IFU)	Risk Classification	Basic UDI-DI
<p>Marketing name: FINEVISION HP</p> <p>Commercial name: POD F GF</p> <p>Technical name: PODFGF</p> <p>Aphakic, Multifocal (Trifocal Diffractive), Aspherical, Hydrophobic Acrylic Intraocular Lens</p>	POD F GF	MDN 1104	<p>The posterior chamber intraocular lens is intended to be placed into the capsular bag with an anterior capsulorhexis for the replacement of the human lens to achieve the visual correction of aphakia in adult patients in whom the cataractous lens has been removed.</p> <p>The lens is indicated for adult patients, surgically treated for cataract, with possibly associated presbyopia, who desire improved uncorrected far vision, useful near and intermediate visual functions and reduced spectacle dependence.</p>	Class IIb, Implantable	0541484601001006V

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Intended purpose (as per the IFU)	Risk Classification	Basic UDI-DI
<p>Marketing name: FINEVISION TRIUMF</p> <p>Commercial name: POD L GF</p> <p>Technical name: PODLGF</p> <p>Aphakic, Multifocal (Trifocal Diffractive), Aspherical, Hydrophobic Acrylic Intraocular Lens</p>	POD L GF	MDN 1104	<p>The posterior chamber intraocular lens is intended to be placed into the capsular bag with an anterior capsulorhexis for the replacement of the human lens to achieve the visual correction of aphakia in adult patients in whom the cataractous lens has been removed.</p> <p>The lens is indicated for adult patients, surgically treated for cataract, with possibly associated presbyopia, who desire improved uncorrected far vision, useful near and intermediate visual functions and reduced spectacle dependence.</p>	Class IIb, Implantable	0541484601001006V

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Intended purpose (as per the IFU)	Risk Classification	Basic UDI-DI
<p>Marketing name: FINEVISION HP TORIC</p> <p>Commercial name: POD FT 49P</p> <p>Technical name: PODFT49P</p> <p>Aphakic, Multifocal (Trifocal Diffractive), Toric, Hydrophobic Acrylic Intraocular Lens</p>	<p>POD FT 49P</p>	<p>MDN 1104</p>	<p>The posterior chamber intraocular lens is intended to be placed into the capsular bag with an anterior capsulorhexis for the replacement of the human lens to achieve the visual correction of aphakia in adult patients in whom the cataractous lens has been removed.</p> <p>The lens is indicated for adult patients, with pre-existing astigmatism, surgically treated for cataract, with possibly associated presbyopia, who desire improved uncorrected far vision, useful near and intermediate visual functions and reduced spectacle dependence.</p>	<p>Class IIb, Implantable</p>	<p>0541484601001006V</p>

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Intended purpose (as per the IFU)	Risk Classification	Basic UDI-DI
<p>Marketing name: ISOPURE SERENITY</p> <p>Commercial name: PODS49P</p> <p>Technical name: PODS49P</p> <p>Aphakic, Enhanced Monofocal, Aspherical, Hydrophobic Acrylic Intraocular Lens</p>	PODS49P	MDN 1104	<p>The posterior chamber intraocular lens is intended to be placed into the capsular bag with an anterior capsulorhexis for the replacement of the human lens to achieve the visual correction of aphakia in adult patients in whom the cataractous lens has been removed.</p> <p>The lens is indicated for adult patients, surgically treated for cataract, with possibly associated presbyopia, who desire improved uncorrected far vision, and an extended depth of focus from distance to intermediate, with reduced spectacle dependence.</p>	Class IIb, Implantable	0541484601001006V

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Intended purpose (as per the IFU)	Risk Classification	Basic UDI-DI
<p>Marketing name: ISOPURE SERENITY TORIC</p> <p>Commercial name: PODST49P</p> <p>Technical name: PODST49P</p> <p>Aphakic, Enhanced Monofocal, Toric, Aspherical, Hydrophobic Acrylic Intraocular Lens</p>	PODST49P	MDN 1104	<p>The posterior chamber intraocular lens is intended to be placed into the capsular bag with an anterior capsulorhexis for the replacement of the human lens to achieve the visual correction of aphakia in adult patients in whom the cataractous lens has been removed.</p> <p>The lens is indicated for adult patients, with pre-existing astigmatism surgically treated for cataract, with possibly associated presbyopia, who desire improved uncorrected far vision, and an extended depth of focus from distance to intermediate, with reduced spectacle dependence.</p>	Class IIb, Implantable	0541484601001006V

Additional Information:

PODEYE: Spherical equivalent power at IOL plane (diopter increments): 0D to +9D (1 steps); +10D to +30D (0.5D steps); +31D to +35D (1D steps)

PODEYE TORIC: Spherical equivalent power at IOL plane (diopter increments): +6D to +30D (0.5D steps)
Cylinder power IOL plane (diopter increments): 1.00D; 1.50D; 2.25D; 3.00D; 3.75D; 4.50D; 5.25D; 6.00D

POD F GF: Spherical equivalent power at IOL plane (diopter increments): +6D to +35D (0.5D steps)
Additional Power at IOL plane (diopters): +3.50D and +1.75D

POD L GF: Spherical equivalent power at IOL plane (diopter increments): +10D to +35D (0.5D steps)
Additional Power at IOL plane (diopters): +3.50D and +1.75D at IOL plane

POD FT 49P: Spherical equivalent power at IOL plane (diopter increments): +6D to +35D (0.5D steps)
Cylinder power IOL plane (diopter increments): 1.00D; 1.50D; 2.25D; 3.00D; 3.75D; 4.50D; 5.25D; 6.00D
Additional Power at IOL plane (diopters): +3.50D and +1.75D

PODS49P: Spherical equivalent power at IOL plane (diopter increments): +10D to +30D (0.5D steps); +31D to +35D (1D steps)

PODST49P: Spherical equivalent power at IOL plane (diopter increments): +10D to +30D (0.5D steps); +31D to +35D (1D steps)
Cylinder power IOL plane (diopter increments): 1.00D; 1.50D; 2.25D; 3.00D; 3.75D; 4.50D; 5.25D; 6.00D