

Device Schedule:

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Intended purpose (as per the IFU)	Risk Classification	Basic UDI-DI
<p>Marketing name: MICROPURE</p> <p>Commercial name: MICROPURE</p> <p>Technical name: MICAGF</p> <p>Aphakic, Monofocal, Aspherical, Hydrophobic Acrylic Intraocular Lens</p>	MICROPURE	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, who desire improved uncorrected far vision.</p>	Class IIb, Implantable	05414846010020072
<p>Marketing name: MICROPURE 123</p> <p>Commercial name: MICROPURE 123</p> <p>Technical name: MICAGF123I</p> <p>Preloaded Aphakic, Monofocal, Aspherical, Hydrophobic Acrylic Intraocular Lens</p>	MICROPURE 123	MDN 1104		Class IIb, Implantable	05414846010020072

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</p> <p>Commercial name: ISOPURE</p> <p>Technical name: MICIGF</p> <p>Aphakic, Enhanced Monofocal, Aspherical, Hydrophobic Acrylic Intraocular Lens</p>	ISOPURE	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	05414846010020072
<p>Marketing name: ISOPURE 123</p> <p>Commercial name: ISOPURE 123</p> <p>Technical name: MICIGF123I</p> <p>Preloaded Aphakic, Enhanced Monofocal, Aspherical, Hydrophobic Acrylic Intraocular Lens</p>	ISOPURE 123	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	05414846010020072

Additional Information:

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

MICROPURE 123 : Spherical equivalent power at IOL plane (diopter increments): 0D to +9D (1D steps); +10D to +30D (0.5D steps)

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

ISOPURE 123 : Spherical equivalent power at IOL plane (diopter increments): +10D to +30D (0.5D steps)