

## Technical data Sheet I-Stream x

Product code: ISP60X + diopter

Model: I-Stream x

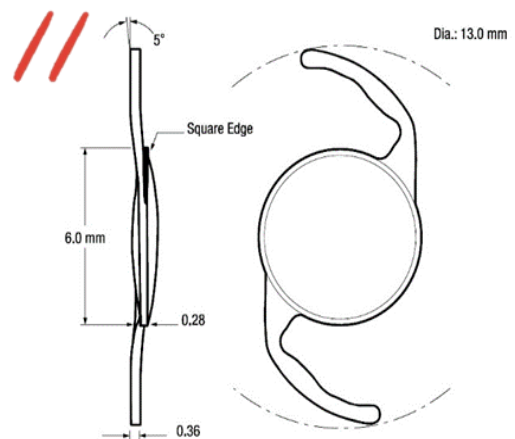
Manufacturer: Md Tech Srl - Via Fratelli Bandiera, Ncc - 80026 Casoria (Na), Campania Italia

Intended Use: Cataract surgery

Use: Intraoperative ophthalmic use

Italian Registration Number: 1514049

One-piece preloaded hydrophobic acrylic lens with aspherical front surface with Glare Stop Barrier filter.



### // General Features

<b>Material</b>	Hydrophobic acrylic with UV filter with water content <1%, biocompatible with eye tissue
<b>Lens Geometry</b>	Biconvex optic, Monofocal, Aspheric, Square Edge 360°.
<b>Dioptric Range</b>	from -5.0D a + 10.0D with increment of 1D; from +10.5D to +30.5D with increment of 0.5 Dpt; from +31.0 to 40.0 with increment of 1D
<b>Incision</b>	from 2,2mm with preloaded screw type Medical injector

### // Optical Features

<b>Optic Diameter</b>	6.0mm
<b>Total Diameter</b>	13.0mm
<b>Sferical Aberration</b>	-0,26 $\mu$ m
<b>Color</b>	Clear
<b>Refractive Index</b>	1,56
<b>UV Filter</b>	White UV CUT OFF < 10% @370nm
<b>A Costant</b>	118
<b>Constant with Ulib System</b>	SRK/T = 118,8; SRK/2 = 119,1; Holladay1 sf = 1,66; Holladay 2 = 5,432; Barrett = 1,78 HofferQ pACD = 5,45; Haigis a0 = 1,26; a1 = 0,40; a2 = 0,10

## // Haptics Features

<b>Type</b>	Optical disc and haptics without profile discontinuity
<b>Haptic Angulation</b>	5° for a long term better stability in the capsular bag

## // Other Specifications

<b>Reference Standard</b>	Directive 93/42 CEE, UNI EN ISO:11979
<b>Class</b>	II b Certiquality Srl, Notified Body n°0546, certif. N.18539/1/I
<b>Control Performed</b>	DIOPTER , MTF, Cosmetic
<b>Packaging</b>	Each lens is preloaded in a screw type injector packed in a polypropylene blister closed in a tyvek pouch. Each pouch is contained in a carton box with administrative label.
<b>Product Type</b>	Medical device in compliance with the current legislation
<b>Compatibility With Solutions</b>	Product can be used with hyaluronic acid, balanced salt solution. It must not be used with acid or melted with other substances.
<b>Shelf Life and Sterilization Method</b>	Product has 60 months of validity from sterilization date and until the date declared on label. Sterilized with EtO according to UNI EN ISO 11135. Product cannot be re-sterilized.
<b>Tests</b>	In vitro cytotoxicity tests, allergic sensitization tests on guinea pigs, eye irritation tests on guinea pigs, product stability tests have been carried out on the product in the experimental phase (reports available in the company)
<b>Presence of Latex</b>	No
<b>Storage</b>	Store at ambience condition, in dry place without humidity. Temperature must be in the range +5°C and+45°.
<b>Information Reported on the Packaging</b>	Batch number, expiry date, serial number, sterilization, manufacturer, CE mark.

