



DEVICE DETAILS

NAME OF DEVICE	TEK-LENS II THREE PIECE HYDROHILIC ACRYLIC INTRAOCULAR LENS
ESTABLISHMENT NAME	TRANSMEDIC HEALTHCARE SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC8612022-84228
BRAND NAME	TEKIA
MEDICAL DEVICE CATEGORY	MD 0203 - Non-active functional implants
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	TEKIA 3 piece hydrophilic acrylic IOLs are foldable intraocular lenses(IOL's) designed to be implanted in place of the natural lens after extracapsular cataract extraction. They consist of an hydrophilic acrylic optic lathed and milled from a HEMA/ MMA copolymer material containing a UV blocker and which foldability is obtained through hydration. The yellow (Y) IOLs series are manufactured from the same hydrophilic acrylic material which includes additionally a blue light blocker.
DEVICE INTENDED PURPOSE	TEKIA 3 piece hydrophilic acrylic IOLs are designed to be implanted in the posterior chamber of the eye after the extraction of cataract in the following conditions: senile cataract, traumatic cataract, congenital cataract.
VALIDITY DATE OF REGISTRATION	24/01/2022 - 23/01/2027



LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Tek-Lens™ II Three Piece Hydrophilic Acrylic Intraocular Lenses	617
2	Tek-Lens™ II Three Piece Hydrophilic Acrylic Intraocular Lenses	617Y
3	Tek-Lens™ II Three Piece Hydrophilic Acrylic Intraocular Lenses	618
4	Tek-Lens™ II Three Piece Hydrophilic Acrylic Intraocular Lenses	618Y