MEDICONTUR

DECLARATION OF CONFORMITY

We hereby declare under our exclusive responsibility that the products listed below comply with the requirements of the European Medical Device Directive 93/42/EEC, as well as with the other applicable laws, regulations and directives. Design and manufacturing are in compliance with the applicable harmonized standards published in the Official Journal of the European Union. All supporting documentation – including the list of applicable standards – is retained at the premises of the manufacturer.

Manufacturer: MEDICONTUR Medical Engineering Ltd.
Herceghalmi Road, H-2072 Zsámbék, Hungary

Product identification:

Hydrophilic acrylic IOL for implantation into the capsular bag:
125DS

Aspheric hydrophilic acrylic IOL for implantation into the capsular bag:

18AL	125DA	600HPS	601HP	610HPS	611HPS	612HPS
640AB	640P*	640PM*	677AB	677P*	677TA	677PT*
677TB	677PTB*	677M	677PM*	677MT	677PMT*	690AB
690P*	690TA	690PT*	690TB	690PTB*	690M	690PM*
690MT	690PMT*	UTH1				

Aspheric hydrophilic acrylic IOL with blue light filter for implantation into the capsular bag:

18ALY	125DY	640ABY	640PY*	640PMY*	640MY	677ABY
677PY*	677TAY	677PTY*	677TBY	677PTBY*	677MY	677PMY*
677MTY	677PMTY*	690ABY	690PY*	690TAY	690PTY*	690TBY
690PTBY*	690MY	690PMY*	690MTY	690PMTY*		

Hydrophilic acrylic IOL for implantation into the ciliary sulcus:

A46R	A45RT	A45RD2	A45SML	A45DT

Hydrophilic acrylic IOL with blue light filter for implantation into the ciliary sulcus:
A45SMY

Aspheric hydrophobic acrylic IOL for implantation into the capsular bag:

860FAB	860PA**	877FAB	877PA**

Aspheric hydrophobic acrylic IOL with blue light filter for implantation into the capsular bag:

860FABY	860PAY**	877FABY	877PAY**

PMMA IOL for implantation into the capsular bag:

76 MP	505MP	552MP	600MP	601MP	602MP	609MP
653MP	656MP	700MP				

PMMA IOL for implantation into the anterior chamber:
91A

* preloaded intraocular lens for Medjet preloaded injection system
** preloaded in a single use injector

Classification: Class IIb according to Annex IX of 93/42/EEC rule 8
Notified Body: SGS United Kingdom Ltd., 202BWorle Parkway, Weston-super-Mare, BS22 6WA, UK
Notified Body Number: 0120
CE Certificate: HU14/7098

Zsámbék,
04. DEC. 2018

Digitally signed by Bolocan Vladimir
Date: 2019.03.28 09:52:26 EET
Reason: MoldSign Signature
Location: Moldova

MEDICONTUR
Medical Engineering Ltd
Herceghalmi Road • H-2072 Zsámbék

Botond Bodosi
Quality Manager