

**DECLARATION OF CONFORMITY**

We, the manufacturer herewith declare that the products listed below comply with the requirements of the Directive 93/42/EEC as amended by 2007/47/EC, that the conformity assessment procedures are completed according to Annex II excluding section 4 of 93/42/EEC as amended by 2007/47/EC. 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	LR01			

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
------	-------	--------	--------

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

Aspheric hydrophobic acrylic IOL for implantation into the capsular bag:

22FAB	860FAB	860PA**	877FAB	877PA**
-------	--------	---------	--------	---------

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

22FABY	860FABY	860PAY**	877FABY	877PAY**
--------	---------	----------	---------	----------

3-pieces hydrophilic acrylic IOL for implantation into the capsular bag:

623PES

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. Notified Body Number: 0120  
**CE Certificate:** HU14/7098

Zsámbék, 10/FEB/2016

**MEDICONTUR**  
Medical Engineering Ltd  
Herceghalmi Road - H-2072 Zsámbék

**Botond Bodosi**  
Quality Assurance Manager