MEDICONTUR

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:

Sterile single use foldable lens injectors:

Medjet MC$^{1.6}$	Disposable Injection Kit
Medjet MB$^{1.8}$	Disposable Injection Kit
Medjet MA$^{2.2}$	Disposable Injection Kit
Medjet MX$^{2.4}$ HB	Disposable Injection Kit
Medjet B1B$^{2.2}$	Single use injector
Medjet PIL-MA	Single use injection system for preloaded hydrophilic intraocular lenses

Classification: Class IIa according to Annex IX of 93/42/EEC rule 6

Notified Body: SGS United Kingdom Ltd. Notified Body Number: 0120

CE Certificate: HU14/7098

Zsámbék,

04. DEC. 2018

Digitally signed by Bolocan Vladimir
Date: 2019.03.28 09:53:30 EET
Reason: MoldSign Signature
Location: Moldova

MEDICONTUR
Medical Engineering Ltd
Herceghalmi Road • H-2072 Zsámbék

Botond Bodosi
Quality Manager