

EC Certificate Full Quality Assurance System: HU14/7098

The management system of

# MEDICONTUR Medical Engineering Ltd.

2072 Zsámbék, Herceghalmi út 1. Hungary

has been assessed and certified as meeting the requirements of

## **Directive 93/42/EEC**

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 15 July 2017 until 2 May 2022 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 02 May 2020

Issue 20. Certified since 20 May 1997

Certification is based on reports numbered HU164QYH

This is a multi-site certification. Additional site details are listed on the subsequent page.

Authorised by



#### SGS United Kingdom Ltd, Notified Body 0120

SGS United Kingdom Ltd Systems & Services Certification 202B Worle Parkway, Weston-super-Mare, BS22 6WA UK t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

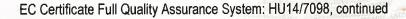
SGS CE 02 0315 M2

Page 1 of 2





This document is Issued by the Company subject to its General Conditions of Certification Services accessible at www.sgs.com/terms\_and\_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at <a href="http://hwww.sgs.com/en/certified-clients-and-products/certified-client-directory">http://hwww.sgs.com/en/certified-clients-and-products/certified-client-directory.</a>
Any unauthorized afteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest





# MEDICONTUR Medical Engineering Ltd.

### **Directive 93/42/EEC**

on medical devices, Annex II (excluding section 4) Issue 20

Detailed scope

Annex II (excluding Section 4)

Sterile PMMA intra ocular lenses and capsular tension rings
Sterile foldable hydrophilic and hydrophobic intra ocular lenses and iris
diaphragm

Sterile single use injector kits for intra ocular lenses, capsular tension rings and iris diaphragm - preloaded and not preloaded

Sterile Viscoelastic solutions for ophthalmic use

Sterile Capsular Tension Ring Preloaded In A Single Use Injection Kit

Steril PMMA lencsék és szemészeti implantátumok, Steril elasztikus hidrofil és hidrofób akril lencsék és szemészeti implantátumok,

Steril egyszer használatos elasztikus lencse és szemészeti implantátum injektorok,

Steril egyszer használatos elasztikus lencse injektorok, Szemészeti felhasználásra szánt steril viszkoelasztikus oldatok, Steril egyszer használatos tokfeszítő gyűrűvel előre töltött injektor kitek

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market

Additional facilities

H-2072 Zsámbék, Táncsics u.1. Hungary H-1123 Budapest, Csörsz u. 13. Hungary H-1124 Budapest Tamási Áron utca 38. Hungary