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
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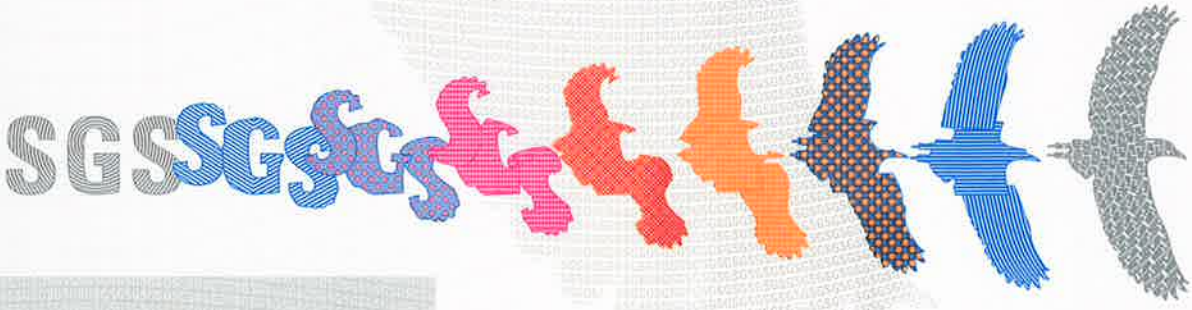
SGS CE 02 0315 M2



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