EC Certificate Full Quality Assurance System: Certificate US12/82416.01

The management system of

EyeKon Medical, Inc.
Trading as EyeKon

2451 Enterprise Road,
Clearwater, FL, 33763, United States

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

Sterile PMMA, hydrophilic, and hydrophobic acrylic intra-ocular lenses, sterile capsular tension rings, and sterile viscoelastic solutions for ophthalmic surgery.

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.

This certificate is valid from 13 January 2016 until 5 July 2020
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 5 July 2019
Issue 4. Certified since 4 March 2003

Certification is based on reports numbered WW/ME 603896

Multiple certificates have been issued for this scope
The main certificate is numbered US12/82416.00

Authorised by

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"LENSES GRUP" S.R.L. Nr. 1003600069773