

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

**APX Ophthalmology
25 Yefe Nof Street
Haifa, 3437113
Israel**

for the scope

**Sterile single patient single use device for
mechanical pupil expansion in intraocular surgery**

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system
meets all requirements according to

**Annex II – excluding Section 4
of the Council Directive 93/42/EEC**

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2017-01-13
Valid until	2022-01-13
Registration no.	D1408000002
Report no.	P16-01674-85675
Stuttgart	2017-01-13



Head of Certification Body

