

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

**APX Ophthalmology Ltd.
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	2018-11-30
Valid until	2023-11-30
Registration no.	D1408000004
Report no.	P18-01182-128228
Stuttgart	2018-10-30



Head of Certification Body

