

Supplement to the Certificate
according to 93/42/EEC, Annex II, excluding 4
Page 1 of 1

Manufacturer	Samsara Vision Ltd.
Certificate	No. D1027100016 Date: 2020-04-24 Implantable Miniature Telescopes (WA 2.2X, WA 3X, WA-DE 3X, NG IMT, Tsert SI (NG SI IMT 3X))
Products concerned	Implantable Miniature Telescopes (WA 2.2X, WA 3X, WA-DE 3X, NG IMT, Tsert SI (NG SI IMT 3X))
Intended change	Change of company name OLD: VisionCare Ophthalmic Technologies Ltd. NEW: Samsara Vision Ltd. Change of brand name OLD: Tsert Si NEW: SING IMT Change of certificate scope OLD: Implantable Miniature Telescopes (WA 2.2X, WA 3X, WA-DE 3X, NG IMT, Tsert SI (NG SI IMT 3X)) NEW: Implantable Miniature Telescopes (WA 2.2X, WA 3X, WA-DE 3X, NG IMT, SING IMT (NG SI IMT 3X))
Review report no.	P22-00624-241902

The intended change is in compliance with the requirements of the Directive 93/42/EEC.

This supplement is valid only in conjunction with the aforementioned Certificate.

The aforementioned Certificate is valid only in conjunction with this supplement.

This supplement is valid until: 2024-05-26
Registration no.: D1027100018
Stuttgart 2022-06-30


Head of Notified Body



EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

**VisionCare Ophthalmic Technologies Ltd.
21 Yegia Kapayim St., P.O.B. 3879
Petah Tikva, 4913020
Israel**

for the scope

**Implantable Miniature Telescopes
(WA 2.2X, WA 3X, WA-DE 3X, NG IMT, Tsert SI (NG SI IMT 3X))**

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	2020-04-24
Valid until	2024-05-26
Registration no.	D1027100016
Report no.	P19-00937-150759
Stuttgart	2020-04-24



Head of Certification Body

