

Supplement to the EC Declaration of Conformity (Ref:100186016 Rev 10)

According to 93/42/EEC, Annex II, Excluding 4

Manufacture	Samsara Vision Ltd.
EC Declaration of Conformity	Document No. 100186016 Rev 10 product List: see on DoC Rev 10*
Product concern	Implantable Miniature Telescope (by Dr. Isaac Lipshitz) Models: WA 2.2X, WA 3X, WA-DE 3X, NG IMT, Tsert (NG SI IMT 3X)
Intended Change	<u>Change of company name :</u> Old : VisionCare Ophthalmic Technologies Ltd. New : Samsara vision Ltd <u>Change of Brand name :</u> Old : Tsert SI™ system New : SING IMT™ Model : NG SI IMT 3X <u>Change of EC Declaration of Conformity :</u> WA 2.2X, WA 3X, WA-DE 3X, NG IMT, SING IMT (Model: NG SI IMT 3X)

* New Catalogue Ref. numbers identified in the attached Product List.

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

The devices listed in the attached product list fall under the scope of Art. 120 of the Regulation (EU) 2017/745

This supplement is valid in conjunction with the aforementioned EC DoC 100186016 Rev 10.

The aforementioned EEC DoC 100186016 Rev 10 is valid only in conjunction with this supplement

This supplement is valid until: 2027-12-31

Raya Melichi

Director, QA/RA

Signature

Raya Melichi
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Place: Petah Tikva, Israel issue date: Dec. 03, 2024

Product List

No	Product Name	Commercial name / Model designation	Catalogue reference number	BASIC UDI - DI
1	Implantable Miniature Telescope (by Dr. Isaac Lipshitz)	WA 2.2X	PR00042-00	7290018786WA2X000423Y
2	Implantable Miniature Telescope (by Dr. Isaac Lipshitz)	WA 3X	PR00043-00	7290018786WA3X000434K
3	Implantable Miniature Telescope (by Dr. Isaac Lipshitz)	WA-DE 3X	PR00043-DE	7290018786WADE000435C
4	Implantable Miniature Telescope (by Dr. Isaac Lipshitz)	NG IMT	PR00035-00	7290018786NG000354G
5	Implantable Miniature Telescope (by Dr. Isaac Lipshitz) - English	SING IMT™, NG SI IMT 3X	PR00118-00	7290018786NGSI00118C8
6	Implantable Miniature Telescope (by Dr. Isaac Lipshitz) - German	SING IMT™, NG SI IMT 3X	PR00121-00	
7	Implantable Miniature Telescope (by Dr. Isaac Lipshitz) - French	SING IMT™, NG SI IMT 3X	PR00122-00	
8	Implantable Miniature Telescope (by Dr. Isaac Lipshitz) - Italian	SING IMT™, NG SI IMT 3X	PR00123-00	
9	Implantable Miniature Telescope (by Dr. Isaac Lipshitz) - Spanish	SING IMT™, NG SI IMT 3X	PR00124-00	
10	Implantable Miniature Telescope (by Dr. Isaac Lipshitz) - Portuguese	SING IMT™, NG SI IMT 3X	PR00125-00	
11	Implantable Miniature Telescope (by Dr. Isaac Lipshitz) - Dutch	SING IMT™, NG SI IMT 3X	PR00126-00	
12	Implantable Miniature Telescope (by Dr. Isaac Lipshitz) - Greek	SING IMT™, NG SI IMT 3X	PR00127-00	
13	Implantable Miniature Telescope (by Dr. Isaac Lipshitz) - Swiss	SING IMT™, NG SI IMT 3X	PR00130-00	
14	Implantable Miniature Telescope (by Dr. Isaac Lipshitz) - Turkish	SING IMT™, NG SI IMT 3X	PR00134-00	
15	Implantable Miniature Telescope (by Dr. Isaac Lipshitz) - Belgium	SING IMT™, NG SI IMT 3X	PR00137-00	
16	Implantable Miniature Telescope (by Dr. Isaac Lipshitz) - Polish	SING IMT™, NG SI IMT 3X	PR00138-00	
17	Implantable Miniature Telescope (by Dr. Isaac Lipshitz) - Norway	SING IMT™, NG SI IMT 3X	PR00139-00	
18	Implantable Miniature Telescope (by Dr. Isaac Lipshitz) - Romania	SING IMT™, NG SI IMT 3X	PR00140-00	
19	Implantable Miniature Telescope (by Dr. Isaac Lipshitz) - Hungary	SING IMT™, NG SI IMT 3X	PR00141-00	
20	Implantable Miniature Telescope (by Dr. Isaac Lipshitz) - Czech	SING IMT™, NG SI IMT 3X	PR00142-00	
21	Implantable Miniature Telescope (by Dr. Isaac Lipshitz) - Slovakia	SING IMT™, NG SI IMT 3X	PR00145-00	
22	Implantable Miniature Telescope (by Dr. Isaac Lipshitz) - Croatia	SING IMT™, NG SI IMT 3X	PR00146-00	
23	Implantable Miniature Telescope (by Dr. Isaac Lipshitz) - Bulgaria	SING IMT™, NG SI IMT 3X	PR00147-00	