

EC Declaration of Conformity (Medical Devices)

Manufacturer's Name:	VisionCare Ophthalmic Technologies Ltd.
Manufacturer's Address:	21 Yegia Kapayim Street, Petah Tikva 4913020, Israel
Name of Device:	Implantable Miniature Telescope ^(by Dr. Isaac Lipshitz) identified in the attached Product List
Device Item Numbers:	See attached Product List
Classification:	Class IIb according to Rule 8 of Annex IX of Council Directive 93/42/EEC.
Conformity Assessment Route:	Annex II excluding Section 4.
GMDN Code (If applicable)	58434
SRN (Single Registration Number):	IL-MF-000018630
Notified Body:	mdc medical device certification GmbH Kriegerstrasse 6 70191 Stuttgart Germany Identification Number: 0483
European Authorized Representative	Obelis s.a., Bd. Général Wahis 53, B-1030 Brussels, Belgium Phone: +32.2.732.59.54, E-mail: mail@obelis.net

This declaration is issued under our sole responsibility and we declare hereby that the medical device(s) specified above meet the applicable provisions of Annex I (Essential Requirements) of the Council Directive No. 93/42/EEC for Medical Devices.

All supporting documentation is retained at the premises of the manufacturer.

Ran Amos
QA/RA Director (PRRC)

Signature


VisionCare
Ophthalmic Technologies LTD.

Issue Date: Jan 05, 2021
Place: Petah Tikva, Israel
Valid until: May 26, 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	Tsert SI™ system; NG SI IMT 3X	PR00118-00	7290018786NGSI00118C8
6	Implantable Miniature Telescope (by Dr. Isaac Lipshitz) -German	Tsert SI™ system; NG SI IMT 3X	PR00121-00	
7	Implantable Miniature Telescope (by Dr. Isaac Lipshitz) -French	Tsert SI™ system; NG SI IMT 3X	PR00122-00	
8	Implantable Miniature Telescope (by Dr. Isaac Lipshitz) -Italian	Tsert SI™ system; NG SI IMT 3X	PR00123-00	
9	Implantable Miniature Telescope (by Dr. Isaac Lipshitz) -Spanish	Tsert SI™ system; NG SI IMT 3X	PR00124-00	
10	Implantable Miniature Telescope (by Dr. Isaac Lipshitz) -Portuguese	Tsert SI™ system; NG SI IMT 3X	PR00125-00	
11	Implantable Miniature Telescope (by Dr. Isaac Lipshitz) -Dutch	Tsert SI™ system; NG SI IMT 3X	PR00126-00	
12	Implantable Miniature Telescope (by Dr. Isaac Lipshitz) - Greek	Tsert SI™ system; NG SI IMT 3X	PR00127-00	