

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:
240653-2017-CE-IND-NA-PS Rev. 01

Project No.:
PRJC-548743-2016-MSL-IND

Valid Until
03-November-2022

This is to certify that the quality system of:

Freedom Ophthalmic Pvt. Ltd.

Plot No. 31, Phase-I, SIPCOT Industrial Complex,
Hosur – 635 126, Tamilnadu, India.

For design, production and final product inspection/testing of:

OPHTHALMIC MEDICAL DEVICES

Has been assessed with respect to:

**The conformity assessment procedure described in Annex II
excluding section 4 of Council Directive 93/42/EEC on Medical
Devices, as amended**

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 24 March 2021

For the issuing office:
Notified Body 2460
DNV Product Assurance AS



Mariann Jeremiassen
Principal Assessor

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

ICP-4-5-11-MDD-f2, rev.0

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	2017-11-03
1.0	Extension in scope - new models (in bold) added	2021-03-24

Products covered by this Certificate:

Product Description	Product Name	Class
PMMA Intraocular Lens	PCC 503, PMC 524, PMC 553, PCC 553, PCC 603H, PMC 602, PMC 602H, PMC 652H, PSF 651, PMS 603, PMS 602, PMC 523SQA, PMC 553SQA, PMC 603HSQA, PMC 523SQYA, PMC 553SQYA, PMC603 HSQYA, FIC 5585H in FREEDOM LENS, FREEDOM EDGE, FREEDOM GOLD, FREEDOM POWER, FREEDOM -I JET, FREEDOM IRIS Brands	IIb
Hydrophilic Acrylic Foldable Intraocular Lens With or Without Injector & Cartridge	HFC 603, HFM 606, HFR 574, HFR 603, HFR 573, AFC 603SQ, AFM 606SQ, AFR 603SQ, AFC 603SQY, AFM 606SQY, AFR 603SQY, AFC 602SQ, ICL120, ICL130, ICL225, ICLT 120, ICLT 130, ICLT 225 in FREEDOM FOLD, FREEDOM ICON, FREEDOM FOCUS, FREEDOM ELITE, FREEDOM -I JET, FREEDOM FOCUS, FREEDOM ICL Brands	IIb
Hydrophobic Acrylic Foldable Intraocular Lens With or Without Injector & Cartridge	FPL 602, FPL 603, FPL 573, FPL 602SQ, FPL 603SQ, FPL 573SQ, FPL 573Y, FPL 602Y, FPL 603Y, FPL 602SQY, FPL 603SQY, FPL 573SQY, FPM606SQ, FPL621, FPLS602SQ, 3HPC630, 3HPC640, TPC602SQ, TPC602SQY, MPC602SQ, MPC602SQY, TRPC602SQ, TRPC602SQY, MTPC602SQ, TRTPC602SQ, TRTPC602SQY, EDOF602SQ, FPL602SQP, FPM606SQP, FPL621P, FPL602SQYP, FPLS602SQP, TPC602SQP, TPC602SQYP, MPC602SQP, MPC602SQYP, TRPC602SQP, TRPC602SQYP, MTPC602SQP, TRTPC602SQP, TRTPC602SQYP, EDOF602SQP in FREEDOM ACE, FREEDOM ZEN, FREEDOM ACE +, FREEDOM ZEN +, FREEDOM -I JET, FREEDOM ACE, FREEDOM ARC, FREEDOM SULCO, FREEDOM TORIC, FREEDOM TORYC, FREEDOM MULTIFOCAL, FREEDOM MULTYFOCAL, FREEDOM TRIFLEX,	IIb

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

ICP-4-5-i1-MDD-f2, rev.0

	FREEDOM TRYFLEX, FREEDOM TORIC MULTIFOCAL, FREEDOM TRITORIC, FREEDOM TRITORYC, FREEDOM EDOF, FREEDOM ACE +, FREEDOM ZEN+, FREEDOM ARC +, FREEDOM TORIC +, FREEDOM TORYC +, FREEDOM MULTIFOCAL +, FREEDOM MULTYFOCAL +, FREEDOM TRIFLEX +, FREEDOM TRYFLEX +, FREEDOM TORIC MULTIFOCAL +, FREEDOM TRITORIC +, FREEDOM TRITORYC +, FREEDOM EDOF + Brands	
PMMA Capsular Tension Rings	FCR 1109, FCR 1210, FCR 1311, FCR 1412, FCC 1008L, FCC 1008R, FCC 1008LR, FCC 1210L, FCC 1210R, FCC 1210LR, FCC 1311L, FCC 1311R, FCC 1311LR in FREEDOM RINGS Brand	IIb
Microsurgical Blades with or without Handle and Safety	Keratome Blades (Sharp Tip): FB1024ST, FB1324ST, FB1620ST, FB1920ST, FB2220ST, FB2520ST, FB2820ST, FB3119TH, FB3419ST Keratome Blades (Blunt Tip): FB3518BT, FB3818BT, FB4118BT, FB4418BT, FB4716BT, FB5016BT, FB5316BT, FB5616BT, FB 5915BT, FB6215BT Crescent Blades: FB2020TI, FB2320TI, FB2620TI Lance tip knives: FB1524LT, FB3024LT, FB4524LT MVR Blades: FB19MVR, FB20MVR, FB24MVR in FREEDOM MICRO Brand	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Freedom Ophthalmic Pvt Ltd	Plot No. 31, Phase-I, SIPCOT Industrial Complex, Hosur – 635 126, Tamilnadu, India.

EU Representative

CMC Medical Devices & Drugs S.L.,
C/Horacio Lengo N° 18, CP 29006, Malaga, Spain.
Telephone: +34951214054, Mobile: +34661416622,
email: info@cmcmedicaldevices.es

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. the Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate