EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
240653-2017-CE-IND-NA-PS	**PRJC-548743-2016-MSL-IND**	**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 Article 11.3.a and Annex II excluding section 4 (Module H2) 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.

Digitally signed by Pereteatco Alina
Date: 2022.10.02 17:29:22 EEST
Reason: MoldSign Signature
Location: Moldova

Place and Date:
Høvik, 08 November 2017

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Cathrine Wisbech

Cathrine Wisbech

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

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

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Jurisdiction

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

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	2017-11-03

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 in FREEDOM LENS, FREEDOM EDGE, FREEDOM GOLD, FREEDOM POWER, FREEDOM -I JET 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 in FREEDOM FOLD, FREEDOM ICON, FREEDOM FOCUS, FREEDOM ELITE, FREEDOM –I JET 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 in Freedom Ace, Freedom Zen, Freedom Ace +, Freedom Zen +, FREEDOM –I JET	IIb
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	Keratome Blades (Sharp Tip) FB1024ST, FB1324ST, FB1620ST, FB1920ST,	IIa

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Safety	FB2220ST, FB2520ST, FB2820ST, FB3119ST, 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	

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address	Site Scope
Freedom Ophthalmic Pvt Ltd	Plot No. 31, Phase-I, SIPCOT Industrial Complex, Hosur – 635 126, Tamilnadu, India.	Design, Development, Manufacturing, Distribution of intraocular lens, Intraocular Rings, Injector and Catridges & Ophthalmic Surgical Blades and Marketing & Sales of Ophthalmic Sterile solutions.

EU Representative

CMC Medical Devices & Drugs S.L.,
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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 Presafe of any intended updating of the quality system and Presafe 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. Presafe 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 of Presafe.

End of Certificate