Notified Body Confirmation Letter Reference: C687092

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, DNV Product Assurance AS, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 2460 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Ellis Ophthalmic Technologies Inc.
147-39, 175th Street, Suite #128, Jamaica,
New York, USA

SRN Number: US-MF-000014670

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

Place and date:
Høvik, 06.01.2025

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Menaka Singh
Management Representative

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function.
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device name: Sterile Ophthalmic Intra Ocular Lens - PMMA **Basic UDI-DI:** 08466600PMMAGALALE7 Brand Name : Galaxy Lens Model Name: ES501 ,ES701 ,ES901	**IIb**	**PMMA – IOL** **(Name change Only)**	MDD certificate number: 11330-2017-CE-IND-NA-PS Rev. 1.0 Appendix: Revision 0.0 NoBo Name: DNV Product Assurance As NoBo Number: 2460
Device name: Sterile Ophthalmic Intra Ocular Lens - Foldable Hydrophilic **Basic UDI-DI:** 08466600HPHILICGALAFJ2 Brand Name: Galaxy Fold Model Name: Center Fix, Center Fit, Ultrasmart, Ultrasmart-M , MDIFF	**IIb**	**HYDROPHILIC – IOL** **(Name change Only)**	MDD certificate number: 11330-2017-CE-IND-NA-PS Rev. 1.0 Appendix: Revision 0.0 NoBo Name: DNV Product Assurance As NoBo Number: 2460
Device name: Sterile Ophthalmic Intra Ocular Lens - Foldable Hydrophobic **Basic UDI-DI:** Preloaded-08466600PHPHOBICGALAFSWN	**IIb**	**HYDROPHOBIC – IOL** **(Name change Only)**	MDD certificate number: 11330-2017-CE-IND-NA-PS Rev. 1.0 Appendix: Revision 0.0

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Semi Preloaded - 08466600SPHPHOBICGALAFSNL **GALAXY FOLD SUPERPHOB AE-01** **SUPERPHOB MF AEM-01**			NoBo Name: DNV Product Assurance As NoBo Number: 2460

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
NA	**NA**	**NA**	**NA**

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/05/08	C687092	Initial issue
2024/08/02	C687092	Rev 01, Products moved to table 1, DNV will have surveillance audit responsibility
2025/01/06	C687092	Rev 02, MDD certificate Appendix: Revision 0.0 added which is for “Change of EU Representative”

Lack of fulfilment of conditions

The following may render this letter of confirmation invalid:

- Lack of compliance to the requirements of Regulation (EU) 2023/607.
- Significant changes to design or intended purpose of the devices.
- Changes in the quality system affecting production.
- Periodical audits not held within the timeframe.

DNV·GL

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
11330-2017-CE-IND-NA-PS Rev. 1.0	PRJC-337296-2011-PRC-IND	25 October 2021

This is to certify that the quality system of:

Ellis Ophthalmic Technologies Inc.

147-39. 175 Street, Suite # 128, JAMAICA, NY.11434, USA

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

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, 20 February 2020

NORWEGIAN ACCREDITATION

PROD 021

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Cathrine Wisbech

Cathrine Wisbech

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

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	Supersedes DNV GL (NB 0434) certificate No. 104634-2011-CE-IND-NA 2.0 following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460).	2017-10-27
1.0	**Correction in address (JAMICA to JAMAICA)**	2020-02-20

Products covered by this Certificate:

Product Description	Product Name	Class
PMMA – IOL	• GALAXY LENS • ES501 • ES701 • ES901	IIb
HYDROPHILIC – IOL	• GALAXY FOLD • CENTERFIX • CENTERFIT • ULTRASMART • ULTRASMART-M • MDIFF	IIb
HYDROPHOBIC – IOL	• GALAXY FOLD SUPERPHOB • AE-01 • SUPERPHOB MF-AEM-01	IIb

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Ellis Ophthalmic Technologies Inc.	147-39. 175 Street, Suite # 128, JAMAICA, NY.11434, USA

EU Representative
EMERGO EUROPE, Prinsessegracht 20, 2514 AP The Hague, The Netherlands

Certificate No.:	Project No.:	Valid Until:
11330-2017-CE-IND-NA-PS Rev. 1.0	PRJC-337296-2011-PRC-IND	25 October 2021

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

APPENDIX TO EC CERTIFICATE

Appendix to Certificate no.:
11330-2017-CE-IND-NA-PS Rev. 1.0

Valid Until:
25 October 2021

This is an Appendix issued to EC Certificate issued for manufacturer:
Ellis Ophthalmic Technologies Inc.

originally issued in compliance with:
the Council Directive 93/42/EEC on Medical Devices, as amended

Based on assessment performed, the following changes to the certification has been accepted as compliance with Council Directive 93/42/EEC on Medical Devices has been established.

A new EU representative, replacing the one stated on the certificate, has been accepted.

EU Representative
AMSTERMED B.V Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, The Netherlands.

Appendix History -		
Revision	**Description**	**Issued Date**
0.0	Change of EU Representative	**14 October 2024**

Place and date:
Høvik, 14 October 2024

For the issuing office:
DNV Product Assurance AS - Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Hazem Tinawi
Technical Reviewer