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By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 556174**

Issued To: **CorneaGen Inc.**
101 North Chestnut Street, Suite 303
Winston-Salem
North Carolina
27101
USA

In respect of:

The manufacture of corneal endothelium delivery instruments

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack

Gary E Slack, Senior Vice President - Medical Devices

First Issued: **2010-04-21** Date: **2019-12-11** Expiry Date: **2024-05-26**

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Supplementary Information to CE 556174

Issued To:

CorneaGen Inc.
101 North Chestnut Street, Suite 303
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USA

NBOG code (s)	Device description	Intended purpose per IFU
Class IIa		
MD 0105	EndoSerter corneal endothelium delivery instrument	EndoSerter™ is a sterile, single-use, disposable endothelial delivery instrument. Its use to deliver endothelium during the insertion of allograft tissue during endothelial keratoplastry procedures.

First Issued: **2010-04-21** Date: **2019-12-11** Expiry Date: **2024-05-26**

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 556174**

Date: **2019-12-11**

Issued To: **CorneaGen Inc.**
101 North Chestnut Street, Suite 303
Winston-Salem
North Carolina
27101
USA

Date	Reference Number	Action
21 April 2010	7453974	First issue.
09 April 2015	8254909	Certificate renewal. Change of company name to Ocular Systems LLC and removal of Piedmont Triad Research Park from address. Change of subcontractor name from SteriPro Consulting to SteriPro Laboratories.
23 December 2016	8660044	Company name change from Ocular Systems LLC to SightLife Surgical Inc.
10 April 2017	8712730	Change of EU Representative subcontractor address.
15 August 2018	9629888	Company name change from Sightlife Surgical, Inc. to Corneagen Inc. Removal of subcontractor SteriPro Laboratories.
20 February 2019	7781395	Traceable to NB 0086.
11 December 2019	9754184	Renewal
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
19 August 2024	30182918	Change of legal manufacturer name to CorneaGen, LLC.

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

Inspiring trust for a more resilient world.

19 August 2024

CorneaGen, LLC.
101 North Chestnut Street, Suite 303
Winston-Salem
North Carolina
27101
USA

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 556174	93/42/EEC Annex V	30182918	Change of legal manufacturer name to CorneaGen, LLC.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

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CorneaGen

101 North Chestnut Street, Suite 303

Winston-Salem

North Carolina

27101

USA

31st May 2024

Notified Body Confirmation Letter

Reference: EU2023-607/ 879356

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, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** 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:

CorneaGen
101 North Chestnut Street, Suite 303
Winston-Salem
North Carolina
27101
USA

SRN Number (if available): US-MF-000028846

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 90/385/EEC (AIMDD) or 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/AIMDD 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:

- 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)

On behalf of BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

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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 or 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Endoserter	Class IIa	N/A	MDD Certificate CE 556174 Expires 2024-05-26; Issued by NB 2797

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 or 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2024/05/31	Initial issue