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, 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.
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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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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 556174**
Date:	**2019-12-11**
Issued To:	**CorneaGen Inc.** **101 North Chestnut Street, Suite 303** **Winston-Salem** **North Carolina** **27101** **USA**

Subcontractor:	**Service(s) supplied**
Cathtek, LLC 3825 Reidsville Road Winston-Salem North Carolina 27101 USA	**Manufacture**
Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	**EU Representative**
Sterigenics US, LLC 1148 Porter Avenue Haw River North Carolina 27258 USA	**Gamma Sterilization**

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 556174**

Date: **2019-12-11**

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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.
Current	9754184	Renewal