EC Certificate Full Quality Assurance System: Certificate GB19/964587



The management system of

Duckworth & Kent Ltd

Terence House, 7 Marquis Business Centre, Royston Road, Baldock, Hertfordshire, SG7 6XL, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Phaco range of irrigation and aspirating ophthalmic instruments

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market

This certificate is valid from 01 December 2020 until 24 May 2024 and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 25 January 1996 and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered GB/PC 04406

Authorised by

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antweep Belgium t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5007 - Certificate CE1639 Annex II 4_EN rev. 02

Page 1 of 1





This document is a Web version of SGS certificate for electronic use exclusively. It shall only be available by clicking on SGS Certification Mark which has been posted on Your website. It shall not be printed in anyway. This document is copyright protected. No content or appearance may be reproduced without the express written permission of SGS. Any misuse, alteration, forgery or falsification is unlawful.

SGS

EC Certificate Production Quality Assurance System: Certificate GB19/964585

The management system of

Duckworth & Kent Ltd

Terence House, 7 Marquis Business Centre, Royston Road, Baldock, Hertfordshire, SG7 6XL, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V
Restricted to the aspects of manufacture concerned with the conformity of
the devices with metrological requirements

For the following products

Ophthalmic measuring instruments for use in surgery.

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 16 December 2019 until 24 May 2024 and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 25 January 1996 and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered GB/PC/ 04406

Authorised by

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5008 - Certificate CE1639 AnnexV_EN rev. 01

Page 1 of 1



\$\\ \text{Signature} \t

This document is issued by the Company subject to its General Conditions of Certification Services, unless otherwise agreed, accessible at www.sgs.com/terms_and_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at https://www.sgs.com/en/certified-clients-and-products/certified-client-directory. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.