

EC Certificate Full Quality Assurance System: Certificate HK20/42022

The management system of

Retraction Limited

Flat/RM 1405, 14/F., 135 Bonham Strand Trade Centre, 135 Bonham Strand, Sheung Wan, Hong Kong, P.R. China 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

Sterile REVEEL ENDOSCOPIC RETRACTOR

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 16 January 2020 until 24 May 2024 and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 01 October 2013 and first certified by SGS Belgium NV since 16 January 2020

Certification is based on reports numbered HK/HKG 15279

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

LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

Page 1 of 1





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, forgety or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.