EC Certificate Full Quality Assurance System: Certificate KR19/81826199

The management system of

The Standard Co., Ltd.

120, Gunpocheomdansaneop 2-ro, Gunpo-si, Gyeonggi-do, 15880, Korea

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 marking ink for marking lesion in the gastrointestinal tract during endoscopic procedures (Model: Black Eye);
Sterile submucosal injection agent for inflating lesion in the gastrointestinal track during endoscopic procedures (Model: Blue Eye);
Anti-fog system for maintaining lens clear during laparoscopic surgery (Model: Defogger)

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 19 May 2021 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 04 June 2009

Certification is based on reports numbered KR/SEL 09208

Authorised by

Global Medical Devices Head of Notified Body

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