ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 16 02 91997 004

Manufacturer:

IntroMedic Co., Ltd.
Suite 1102, 1103, 1104, 1105, 1106
41, Digital-ro 31-gil, Guro-gu
Seoul 08375
REPUBLIC OF KOREA

EC-Representative:

Synectics Medical Ltd.
SynMed House
7 The Pavilion Business Centre, 6 Kinetic Crescent
Innova Park, Enfield
EN3 7FJ
UNITED KINGDOM

Product Category(ies):

- Capsule Endoscope System for visualization of the small bowel mucosa as a tool in the detection of abnormalities
- Esophagoscope System for visualization of esophagus mucosa as a tool in the detection of abnormalities

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 74944394

Valid from: 2016-06-07
Valid until: 2019-07-26

Date, 2016-06-07

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Facility(ies):

IntroMedic Co., Ltd.
Suite 1102, 1103, 1104, 1105, 1106, 41, Digital-ro 31-gil, Guro-gu,
Seoul 08375, REPUBLIC OF KOREA

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