ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

ZLG-BS-244.10.08

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 109971 0002 Rev. 00

Manufacturer: **Allwin Medical Devices, Inc**
3305 E Miraloma Ave, #176
Anaheim CA 92806
USA

Product Category(ies): **Balloon Dilators, Dilators and Sets-Facial Renal & Ureteral, Drainage Catheters & Sets, Gastrostomy Tubes, Non Vascular Guidewires, Ovum Pickup Needles, Puncture Needle, Stone Baskets & Extractors, Suprapubic Drainage Sets, Ureteral Catheters, Ureteral Stents, Vitrification straws**

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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 109971 0002 Rev. 00

Report No.: IND2020105

Valid from: 2021-05-21
Valid until: 2024-05-26

Date, - 2021-05-21

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Bunic Gheorghe
Date: 2022.11.24 16:10:43 EET
Reason: MoldSign Signature
Location: Moldova

ZLG BS 244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in class I in sterile conditions, sterilized systems or procedure packs)

No. G1S 109971 0003 Rev. 00

Manufacturer:

Allwin Medical Devices, Inc
3305 E Miraloma Ave, #176
Anaheim CA 92806
USA

Product Category(ies):

Bladder Evacuators, Embryo Transfer Catheter, Hysterosalpingography Catheter, Intra Uterine Insemination Catheters, Track Finder Bulb Irrigator, Ureteral Access Sheaths

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex II. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1S 109971 0003 Rev. 00

Report No.: IND2020105

Valid from: 2021-05-21
Valid until: 2024-05-26

Date, 2021-05-21

Christoph Dicks
Head of Certification/Notified Body

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

TÜV

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11323-01-00

TÜV SÜD Product Service

Certificate

No. Q5 109971 0001 Rev. 00

Holder of Certificate: Allwin Medical Devices, Inc
3305 E Miraloma Ave, #176
Anaheim CA 92806
USA

Facility(ies): Allwin Medical Devices, Inc
3305 E Miraloma Ave, #176, Anaheim CA 92806, USA

see scope of certificate

Allwin Medical Devices
Plot # 223, 230 & 221, Surat Special Economic Zone, Sachin,
Surat 394230, INDIA

see scope of certificate

Certification Mark:

Scope of Certificate: Design, Manufacturing and Sales of disposable medical devices used for Urology, Gastroenterology, Gynecology, Radiology.

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 109971 0001 Rev. 00

Report No.: IND2020105

Valid from: 2021-05-21
Valid until: 2024-05-20

Date, 2021-05-21

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV