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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 058561 0028 Rev. 04

Certificate Holder: **IZI Medical Products, LLC**
5 Easter Court, Suite J
Owings Mills MD 21117
USA

Certification Mark:

Scope of Certificate: **Design and Development, Production, and Distribution of Markers, Disposable Arrays, Sterile Syringes for Radiology, Radiation Therapy and Surgical Procedures; Design and Development, Production and Distribution of Bone Biopsy Needle Sets, Vertebroplasty Needle Sets, Biopsy Access Needles, Breast Lesion Localization Needle and Cannula Sets, Spinal Implants and Associated Manual Surgical Instruments and Spinal Curettes; Distribution of Thermoplastic Masks and Brain Biopsy Cannula**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Health Canada, USA FDA, MHLW / PMDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: **93-350-6164**

Effective Date: **2021-01-12**

Expiry Date: **2021-12-15**

Date of Issue: 2021-01-22

(Tina Israel)
Manager, US Certification Body,
Medical and Health Services

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C E R T I F I C A T E

No. QS6 058561 0028 Rev. 04

Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Canada
- Medical Device Regulations – Part 1- SOR 98/282

Japan
- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820
- 21 CFR Part 821

Facility(ies):
IZI Medical Products, LLC
5 Easter Court, Suite J, Owings Mills MD 21117, USA

Facility Scopes:
Design and Development, Production, and Distribution of Markers, Disposable Arrays, Sterile Syringes for Radiology, Radiation Therapy and Surgical Procedures; Design and Development, Production and Distribution of Bone Biopsy Needle Sets, Vertebroplasty Needle Sets, Biopsy Access Needles, Breast Lesion Localization Needle and Cannula Sets, Spinal Implants and Associated Manual Surgical Instruments and Spinal Curettes. Distribution of Thermoplastic Masks and Brain Biopsy Cannula
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