



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
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ZLG-BS-244.10.08



Product Service

# EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

**No. G2S 058561 0031 Rev. 00**

## Manufacturer

**IZI Medical Products, LLC**

5 Easter Court, Suite J  
Owings Mills MD 21117  
USA

## Product Category(ies):

**Sterile Syringes and Imaging Markers for  
Radiology, Radiation Therapy and Surgical  
Procedures**

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 V. 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. See also notes overleaf.

**Report No.:** 72153904

**Valid from:** 2020-07-03

**Valid until:** 2024-05-26

**Date,** 2020-07-03

Christoph Dicks  
Head of Certification/Notified Body