



**IZI Medical**



**European Communities Council Directive 93/42/EEC as Amended by Directive 2007/47/EC Concerning Medical Devices  
DECLARATION OF CONFORMITY**

**ILUMARK™ NAVIGATION MARKER**

The undersigned declares that the products named and listed on this certificate meet the provisions of this Council Directive which apply to them and the CE mark may be affixed.

**General Product Name:** ILUMARK™ NAVIGATION MARKER

**Plant of Manufacture:** IZI Medical Products, LLC  
5 Easter Ct. Suite J  
Owings Mills, MD 21117

**Intended Use:** For use as an accessory to aid in registration and localization of patient anatomical structures in either open or percutaneous image guided surgery.

**Sterile:** Yes (unless marked unsterile on the label)

**Measuring Function:** None

**EU Notified Body:** TUV SUD Product Service GmbH  
Zertifizierstelle  
Ridlerstrasse 65  
80339 Munchen, Germany  
Identification Number 0123

**EC Certificate:** G2S 058561 0031

**Harmonized Standards:** EN/ISO 13485:2016

**Directive 2007/47/EC Classification, Device Rule:** Class 1, Rule 1

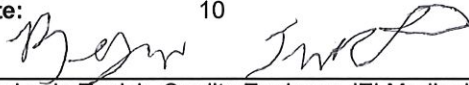
**Product Catalog:**

|                |  |
|----------------|--|
| 2010-XXX-YYYYY | Navigation Marker Snap                                 |
| 2020-XXX       | Navigation Marker Twist                                |
| 2021-XXX       | Navigation Marker Quick Twist                          |
| 1010           | Navigation Marker Snap (unsterile)                     |
| 1020           | Navigation Marker Twist (unsterile)                    |
| 6001           | Navigation Marker half spherical, navigable            |
| 6002           | Insert for Navigation Marker half spherical, navigable |
| 6003           | Navigation Marker, flat, navigable                     |
| 01 007 10      | OEM Marker Snap  |
| 111611         | Spherz Marker  |

XXX defines Set sizes (3, 4, 40, 100, 120, 130, 160, 200)  
YYYYY defines Customer-specific modifier (ORTHO, "None")

**EU Authorized Representative:** Ilumark GmbH  
Hohenlindner Str. 11C  
85622 Feldkirchen  
Germany

**No. of Products covered By this certificate:** 10

**Signed:**   
**Position:** Benjamin Tunick, Quality Engineer, IZI Medical Products, LLC

**Dated:** October 28, 2020