



Product Service

# Certificate

No. Q6 041181 0035 Rev. 01

**Holder of Certificate:** **Biopsybell s.r.l.**  
Via A. Manuzio 24  
41037 Mirandola (MO)  
ITALY

**Facility(ies):** Biopsybell s.r.l.  
Via A. Manuzio 24, 41037 Mirandola (MO), ITALY

**Certification Mark:**



**Scope of Certificate:** Production and distribution of biopsy needles and sets, needles and sets for centring mammary lesions, needles and sets for infusions, biopsy systems, discectomy systems, vertebroplasty systems, kyphoplasty systems, systems for the pre-natal diagnosis and artificial insemination, introduction systems, heat and moisture exchangers (HMEs) for use in humidifying gases during spontaneous breathing, fixing device for catheters, systems for aspiration, processing and reinjection of autologous adipose tissue

**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 (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:** ITA9728031SC

**Valid from:** 2021-02-01

**Valid until:** 2024-01-31

**Date,** 2021-02-08

Stefan Preiß