



Certificate

No. Q6 041181 0035 Rev. 01

Holder of Certificate: **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 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, systems for bone marrow explant**

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). 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:Q6 041181 0035 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q6_041181_0035_Rev.01)

Report No.: ITA1580688

Valid from: 2021-02-01

Valid until: 2024-01-31

Date, 2021-01-08



Christoph Dicks
Head of Certification/Notified Body

Certificate

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

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

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