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

TÜV SÜD Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 041181 0034 Rev. 03

Manufacturer:

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

Product Category(ies):

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, heat and moisture exchangers (hmes) fou use in humidifying the gases during spontaneous breathing, introduction systems, systems for aspiration, processing and reinjection of autologous adipose tissue, systems for bone marrow explant

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: ITA1272058

Valid from: 2020-01-17
Valid until: 2024-05-26

Date, 2020-01-17

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Jighili Tatiana
Date: 2022.10.22 09:45:27 EEST
Reason: MoldSign Signature
Location: Moldova

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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