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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 041181 0033 Rev. 02

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):	**Components for biopsy sets, prenatal diagnosis and artificial insemination, infusions, vertebroplasty and kyphoplasty (syringes, extensions lines, connectors, stopcocks, adaptors, spatulas, bowls, mixing and injection system for cement, inflation devices, tube holders). Fixing device for catheters**

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.: ITA1272058

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

Digitally signed by Iarovoi Petru
Date: 2022.03.17 18:05:06 EET
Reason: MoldSign Signature
Location: Moldova

Date, 2020-01-17

Christoph Dicks
Head of Certification/Notified Body

FIRMA DE PRODUCERE SI COMERT "SOGNO" S.R.L. REPUBLICA MOLDOVA mun.CHISINAU IDNO 1004600013854 Sogno S.R.L.

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

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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

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biopsybell s.r.l.

DICHIARAZIONE DI CONFORMITÀ/ *Declaration of conformity*

Fabbricante: **Biopsybell s.r.l.** Via Manuzio n. 24, 41037, Mirandola (MO), Italy *(Manufacturer)*
Dispositivo Medico *(Medical Device)*: SISTEMI PER VERTEBROPLASTICA/ *VERTEBROPLASTY SYSTEMS*

Famiglia di Prodotto/ Product family	Classe/ Class	Regola/Rule (Allegato IX DDM/ *Annex IX MDD)*
sistemi per VERTEBROPLASTICA / *VERTEBROPLASTY systems*	IIa	6

La Società Biopsybell s.r.l. dichiara sotto la sua sola responsabilità che il Dispositivo Medico STERILE sopra menzionato "SISTEMI PER VERTEBROPLASTICA" e riportato nei codici allegati è conforme ai Requisiti Essenziali della Direttiva Dispositivi Medici 93/42/CEE di cui l'Allegato 1, e successive modificazioni e alle norme applicabili. Il Fascicolo Tecnico contenente la documentazione pertinente è conservato presso il Fabbricante e a disposizione delle Autorità competenti e dell'Ente Notificato (TÜV SÜD PRODUCT SERVICE GMBH Ridlerstr. 65, 80339 München Germany, n°0123). Biopsybell s.r.l. ha sviluppato una procedura per la sorveglianza post - vendita del Dispositivo Medico in accordo al D.M. del 15/11/05 ed alla linea guida europea MEDDEV 2.12/1. La Società BIOPSYBELL s.r.l dichiara inoltre che i dispositivi medici appartenenti al presente fascicolo tecnico rientrano nella gamma di prodotti descritta nel certificato: CE Nr. G20411810034 REV03 e che questo certificate è ancora valido.

Biopsybell s.r.l. declares under its sole responsibility the above mentionned medical device "VERTEBROPLASTY SYSTEMS" indicated in the following codes is conforming to the essential requirements of the Medical Device Directive 93/42/CEE reported in the Annex 1, further amendments and conforming to the applicable rules. The Technical File and supporting documentation are retained under the premises of the Manufacturer at the disposal of the Competent Authorities and Notified Body (TÜV SÜD PRODUCT SERVICE GMBH Ridlerstr. 65, 80339 München Germany, n°0123). Biopsybell s.r.l. has developped a procedure for the vigilance system of the medical devices according to MEDDEV 2.12/1. Biopsybell s.r.l. declares the above mentionned medical devices belonging to this technical file are within the scope of the EC certificate Nr. G20411810034 REV03 and that this EC certificate is still valid.

Direttive Applicabili *(Applicable Directives)*
Direttiva Dispositivi Medici 93/42/CEE (Allegato 5+Allegato7) recepita in Italia dal D.L. n° 46 del 24-02-1997 e successive modificazioni *(Medical Device Directive 93/42/EEC (Allegato 5+Allegato7) transposed in Italy by D.L. n° 46 of the 24-02-1997) and further amendments*

Norme europee armonizzate applicabili (Harmonized European applicable rules)
La lista delle norme applicabili è riportata nel relativo Fascicolo Tecnico FT05 al Cap. 15.
(The list of applicable rules is reported in the Technical File FT05 at Cap. 15)

Ente Notificato: TÜV SÜD PRODUCT SERVICE GMBH *(Notified Body)*
Nr. Ente Notificato: **0123** *(Nr. Notified Body)*

Certificato CE Nr. G20411810034 REV03 *(Certificate Nr.)* Data del Certificato: 17/01/2020 *(Date of Certificate)*
Scadenza: 26/05/2024 *(Expiry date)*

Primo certificato CE rilasciato per il prodotto n° G2D 00 09 41181 001 del 27/09/2000. *First EC certificate released for the products n°G2D 00 09 41181 001 of 27/09/2000.*

Mirandola, 17/01/2020
La presente dichiarazione di conformità è valida fino al 26/05/2024
(The present declaration of conformity is valid until the 26/05/2024
Legal Representative Tiziana Bellini

biopsybell s.r.l.

DICHIARAZIONE DI CONFORMITÀ/ *DECLARATION OF CONFORMITY*

Fabbricante: **Biopsybell s.r.l.** Via A.Manuzio n.24, Mirandola (MO), Italy *(Manufacturer)*

Dispositivo Medico *(Medical Device)*: **ACCESSORI PER MISCELAZIONE E INFUSIONE PER VERTEBROPLASTICA / MIXING AND INFUSION ACCESSORIES FOR VERTEBROPLASTY**

Classificazione (regola 1, Allegato IX DDM): **I sterile**
(Classification rule 1, Annex IX MDD)

La Società Biopsybell s.r.l. dichiara sotto la sua sola responsabilità che il Dispositivo Medico STERILE sopra menzionato **"Accessori per miscelazione e infusione per vertebroplastica"** e riportato nei codici allegati è conforme ai Requisiti Essenziali della Direttiva Dispositivi Medici 93/42/CEE di cui l'Allegato 1, successive modifiche e alle norme applicabili. Il Fascicolo Tecnico contenente la documentazione pertinente è conservata presso il Fabbricante, e a disposizione delle Autorità competenti e dell'Ente Notificato (TÜV SÜD PRODUCT SERVICE GMBH Ridlerstr. 65, 80339 München Germany, n°0123). Biopsybell s.r.l. ha sviluppato una procedura per la sorveglianza post - vendita del Dispositivo Medico in accordo al D.M. del 15/11/05 ed alla linea guida europea MEDDEV 2.12/1.
La Società BIOPSYBELL s.r.l dichiara inoltre che i dispositivi medici appartenenti al presente fascicolo tecnico rientrano nella gamma di prodotti descritta nel certificato: CE Nr. G2S0411810033 REV02 e che questo certificato è ancora valido.
*Biopsybell s.r.l. declares under its sole responsibility that the above mentionned medical device **"Mixing and Infusion Accessories for Vertebroplasty"** "indicated in the following codes is conforming to the essential requirements of the Medical Device Directive 93/42/CEE reported in the Annex 1, further amendments and conforming to the applicable rules. The Technical File and supporting documentation are retained under the premises of the Manufacturer at the disposal of the Competent Authorities and Notified Body* (TÜV SÜD PRODUCT SERVICE GMBH Ridlerstr. 65, 80339 München Germany, n°0123). *Biopsybell s.r.l. has developped a procedure for the vigilance system of the medical devices according to MEDDEV 2.12/1.*
Biopsybell s.r.l. declares the above mentionned medical devices belonging to this technical file are within the scope of the EC certificate Nr. G2S0411810033 REV02 and that this EC certificate is still valid.

Direttive Applicabili
(Applicable Directives)

Direttiva Dispositivi Medici 93/42/CEE (Allegato 5 + Allegato7) recepita in Italia dal D.L. n° 46 del 24-02-1997 e successive modifiche
(Medical Device Directive 93/42/EEC(Annex 5 + Annex 7) transposed in Italy by D.L. n° 46 of the 24-02-1997) and further amendments

Norme europee armonizzate applicabili
(Harmonized European applicable rules)

La lista delle norme applicabili è riportata nel relativo Fascicolo Tecnico FT "11" al Cap. 15.
(The list of applicable rules is reported in the Technical File at Cap. 15)

Ente Notificato: **TÜV SÜD PRODUCT SERVICE GMBH** *(Notified Body)*
Nr. Ente Notificato: **0123** *(Nr. Notified Body)*

Certificato CE Nr. G2S0411810033 REV02 *(Certificate Nr.)*
Data del Certificato: **17/01/2020** *(Date of Certificate)*
Scadenza: **26/05/2024** *(Expiry date)*

Mirandola , 17/01/2020
La presente dichiarazione di conformità è valida fino al 26/05/2024.
(The present declaration of conformity is valid until the 26/05/2024)

Legal Representative
Tiziana Bellini

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