October 16th , 2024

C/0773/24/GF/mab

To: **BIOPSYBELL SRL**
Via Aldo Manuzio, 24 –
41037 - Mirandola - (Modena)

Bureau Veritas Italia SpA

Notified Body Confirmation Letter with reference to the CE Marking Certificates **N° G2S 041181 0033 REV.02** and **N° G2 041181 0034 REV.03 - Directive 93/42/EEC (MDD)**

This letter confirms that, Bureau Veritas Italia SpA, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1370 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement n. 8900080 rev.2 in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

BIOPSYBELL SRL
Via Aldo Manuzio, 24 –
41037 - Mirandola - (Modena)
ITALY

Table n.1

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**Device name under MDD corresponding to the device under MDR application**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application**
KYPHOPLASTY SYSTEMS	IIa	Kyphoplasty system	Certificate N° G2 041181 0034 REV.03, issued by NB n° 0123, on 2020/01/17
VERTEBROPLASTY SYSTEM	IIa	Vertebroplasty system	Certificate N° G2 041181 0034 REV.03, issued by NB n° 0123, on 2020/01/17
SUBCHONDRAL BONE MARROW LESION (BML) SYSTEM	IIa	Needles and sets for infusions	Certificate N° G2 041181 0034 REV.03, issued by NB n° 0123, on 2020/01/17

SYSTEMS FOR METAPHYSEAL FRACTURES	IIa	Needles and sets for infusions	Certificate N° G2 041181 0034 REV.03, issued by NB n° 0123, on 2020/01/17
CEMENT INJECTION SYSTEM FOR MINI-INVASIVE BONE SURGERY	IIa	Introduction system	Certificate N° G2 041181 0034 REV.03, issued by NB n° 0123, on 2020/01/17
ACCESSORIES FOR BONE AUGMENTATION MATERIAL INJECTION	Is	components for vertebroplasty and kyphoplasty systems	Certificate N° G2S 041181 0033 REV.02, issued by NB n° 0123, on 2020/01/17
NEEDLE FOR BIOPSY OR EXPLANT	IIa	System for bone marrow explantat - Needles and sets of centering mammary lesions - Soft tissue biospy needle (semi-automatic); Soft tissue biospy needle (automatic); Soft tissue biospy needle (manual) - Introduction system	Certificate N° G2 041181 0034 REV.03, issued by NB n° 0123, on 2020/01/17
ACCESSORIES FOR BIOPSY OR EXPLANT	Is	biopsy - prenatal diagnosis	Certificate N° G2S 041181 0033 REV.02, issued by NB n° 0123, on 2020/01/17
Discectomy system	IIa	Discectomy system	Certificate N° G2 041181 0034 REV.03, issued by NB n° 0123, on 2020/01/17
System for the aspiration, processing and reijection of autologous adipose tissue	IIa	Components and system for the aspiration, processing and reijection of autologous adipose tissue	Certificate N° G2 041181 0034 REV.03, issued by NB n° 0123, on 2020/01/17
NEEDLES FOR PRE-NATAL DIAGNOSIS AND OOCYTE ASPIRATION	IIa	System for prenatal diasgnosis and artificial insemination	Certificate N° G2 041181 0034 REV.03, issued by NB n° 0123, on 2020/01/17
ANALOG INFLATION DEVICE	Im Is	kyphoplasty inflation device	Certificate N° G2S 041181 0033 REV.02, issued by NB n° 0123, on 2020/01/17

INFUSION SYSTEM	IIa	Needles and sets for infusions	Certificate N° G2 041181 0034 REV.03, issued by NB n° 0123, on 2020/01/17

In accordance with EU Regulation 2023/607 of the European Parliament of the Council of 15 March 2023, Bureau Veritas Italia hereby confirms that:

a. The above-mentioned agreement n° 8900080 rev.2 was signed within 2024/09/26.
b. Bureau Veritas Italia Spa is responsible for the appropriate surveillance of medical devices certified under Directive 93/42/EEC and subsequent amendments, corresponding to medical devices for which an agreement has been signed for certification according to EU Regulation 2017/745 (MDR) as shown in table n.1

As required by EU Regulation 2023/607, the validity of the MDD certificates N° G2S 041181 0033 REV.02 and N° G2 041181 0034 REV.03, is extended until 2028/12/31, assuming that the manufacturer continues to comply with all the applicable conditions specified by EU Regulation 2023/607.

Confirmation Letter Revision History

Date	Revision	Action
2024/10/16	0	Initial Issue

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Cap. Soc. € 4.472.131,00 i.v.
Reg. Imp. e P.IVA 11498640157
Altre Sedi: www.bureauveritas.it/sedi

Soggetta all'attività di direzione e coordinamento da parte di Bureau Veritas SA con sede in Neuilly-sur-Seine - Francia