May 24th , 2024

C/0388/24/GF/mab

To: **CERAGEM Co., Ltd.**
10, JEONGJA 1-GIL – 31045 SEONGGEO-EUP,
SEOBUK-GU, CHEONAN-SI, CHUNGCHEONGNAM DO

Bureau Veritas Italia SpA

Notified Body Confirmation Letter with reference to the CE Marking Certificate **N° IT267961 – 3**
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. 6465578 rev.2 in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

CERAGEM Co., Ltd.
10, JEONGJA 1-GIL – 31045 SEONGGEO-EUP,
SEOBUK-GU, CHEONAN-SI, CHUNGCHEONGNAM DO
REPUBLIC OF KOREA

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**
1.CGM MB-1101 2.CGM MB-1901	IIa	1.CGM MB-1101 2.CGM MB-1901	Certificate N° IT267961 – 3 issued on 2021/01/21
CGM MB-1701 CGM MB-1702	IIa	CGM MB-1701 CGM MB-1702	Certificate N° IT267961 – 3 issued on 2021/01/21
CGM MP-1101	IIa	CGM MP-1101	Certificate N° IT267961 – 3 issued on 2021/01/21

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° 6465578 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 certificate: N° IT267961 – 3 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
2024/05/24	0	Initial issue

Gloria Focetola

GLORIA FOCETOLA - Local Technical Manager

Bureau Veritas Italia S.p.A.
Viale Monza, 347
20126 Milano
www.bureauveritas.it

Tel. (+39) 02 27091.1
Fax (+39) 02 2552980
info.bv.italia@it.bureauveritas.com

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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