CERACARTA® S.p.A.

DECLARATION OF CONFORMITY

Forlì, 7th July 2023

The writing company Ceracarta S.p.a. located in Via Secondo Casadei n° 14, 47122 Forlì, manufacturer of the products named , **"EKOGEL" all sizes and Zerogel *(BASIC UDI-DI* 8059170GC001NG)**,identified and classified in the technical file,declares under its own responsibility that such devices satisfies all the requirements of MDR 2017/745 , about medical devices and in particular that:

• in accordance with enclosure VIII-section III of the MDR the Dispositives in object must be considered as belonging to Class I;

• the Dispositives in object satisfy the essential requirements as in enclosure I of MDR 2017/745;

•the manufacturer has prepared and keeps the technical files updated in accordance with enclosure II of the MDR;

•such documentation is available at the headquarters of Ceracarta , for any reference by the entitled bodies;

•the Dispositive in object must be esclusively used together with electro-medical instruments for recording, diagnosis and therapy, which base their functioning upon the measuring of energy flows of electric, magnetic and ultrasound type;

• Ceracarta S.p.A. has implemented a quality system in accordance with the regulations UNI EN ISO 9001: 2015 and UNI CEI EN ISO 13485:2016.

The president

CERACARTA SPA
Bandini Alessandro

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ISO 9001:2015 EN ISO 13485:2016