

DECLARATION OF CONFORMITY

Forlì, 31st January 2023

The writing company Ceracarta S.p.a. located in Via Secondo Casadei n° 14, 47122 Forlì, manufacturer of the products named , "ECO SUPERGEL" (**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 Dispositivo in object must be exclusively 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

