

---

# DECLARATION OF CONFORMITY

---

Forlì, 13<sup>rd</sup> September 2022

Manufacturer: **Ceracarta S.p.A.**

Address: **Via Secondo Casadei, 14 47122 Forlì - ITALY**

DECLARES

that

**THE RECORDING "THERMAL" AND/OR "INK" PAPERS IN THE MEDICAL FIELD for "ECG", "EEG", "CTG" and papers for laboratory tests (codes 7971,7982,11792,12869, 13097), identified and classified in the Technical file ,comply with the directive about medical devices (DIRECTIVE 93/42/CEE as amended by 2007/47/EC).**

In addition to this, we precise that:

- according to the Directive 93/42/EEC the listed products are medical devices belonging to class I with function of measure.
- they are subject to the regulations of the Attachment I of the above mentioned directive;
- the evaluation of the device was in accordance with Annex V of that Directive, by the certified body IMQ S.p.A. – CE0051;
- 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.

CERACARTA SPA  
Bandini Alessandro

