

DECLARATION OF CONFORMITY

Forlì, 29th February 2024

Producer: **Ceracarta S.p.A**

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

DECLARES

that

THE RECORDING BLANK “THERMAL” AND/OR “INK” PAPERS IN THE MEDICAL FIELD, codes 8597,12090,8605,13108,9516,8615,13108,11735,10907,8625,8605,7955, 9537, 10907,10360,8919,8918,8597,8605,10907,12660,12157,8141,10960,8631 identified and classified in the Technical file, comply with the directive about medical devices (DIRECTIVE 93/42/EEC 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
- they are subject to the regulations of the Attachment I of the above mentioned directive,
- 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

