CERACARTA® S.p.A.

DECLARATION OF CONFORMITY

Digitally signed by Poiata Vitalie
Date: 2022.09.29 12:31:58 EEST
Reason: MoldSign Signature
Location: Moldova

Forlì, 5th August 2022

The writing company Ceracarta S.p.a. located in Via Secondo Casadei n° 14, 47122 Forlì, manufacturer of the products named , **TOP TRACE ECG ELECTRODES *(BASIC UDI-DI* 8059170EL001PR),**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.

In addition:

• the device is tested according to the voluntary Association for the Advancement of Medical Instrumentation (AAMI) standard requirements for electrical performance for disposable ECG electrodes (ANSI/AAMI EC 12:2000) and test results meet or exceed these performance standards.

• the device is tested and it is found to be acceptable for use,according to:

UNI EN ISO 10993-1:"Biological evaluation of medical devices" ;

UNI EN ISO 10993-5 :"Biological evaluation of medical devices :tests for in vitro cytotoxicity";

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ISO 9001:2015

EN ISO 13485:2016

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UNI EN ISO 10993-10 :"Biological evaluation of medical devices :tests for irritation and sensitization".

• Ceracarta does not use any latex/PVC materials or ingredients in the manufacturing of our electrodes;

• 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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