BIODIAGRAM
CARTE DIAGRAMMATE

Digitally signed by Guțan Ghenadie
Date: 2022.09.08 10:05:03 EEST
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SISTEMA DI GESTIONE CERTIFICATO
ITALCERT
UNI EN ISO 9001:2008
UNI CEI EN ISO 13485:2012

EC DECLARATION OF CONFORMITY

ACCORDING TO THE REQUIREMENTS CONTAINED IN 'ANNEX I PROVIDED BY D. LGS. 46/97

AMENDED BY D. LGS. 37/10 - DIRECTIVE RECEPTION 2007/47 / EC, DIRECTIVE CORRECTION 93/42/EC AND REGULATED BY Annex VII OF THIS LAW

The undersigned BIODIAGRAM S.r.l with legal office in Via Bruno Buozzi, 1-80040 San Sebastiano al Vesuvio (NA) and warehouse in Via Boscofangone - 80035 Nola (NA) manufacturer of the medical device called:

CHART PAPERS FOR MEDICAL USE

Code	Description
PXXXXXXXXXXXX/RXXXXXXXXXXXX	**CHART MEDICAL PAPERS**

DECLARES

under its own responsibility that:

- the above device meets all applicable provisions in the above mentioned Directive 2007/47 / EC, Directive correction 93/42 / EEC on Medical Devices
- the medical device is class I* WITH MEASUREMENT FUNCTION, in accordance with Annex IX of Directive 2007/47 / EC, Directive correction 93/42 / EEC;
- for this purpose, a specific CE conformity marking has been issued by the Notified Body no. 0426 with certificate no. 104-01-00-DM
- Biodiagram is committed to preserve and make available to the entities responsible for the dossier Product Technician (FT \ EC \ 02), specified in Appendix V of the Directive Directive 2007/47 / EC, Directive 93/42 / EEC reference to a period of at least five years after the last marketing of the last lot or serial number of specified devices.

It therefore declares that the device concerned is in compliance with the description in Directive 2007/47 / EC, Directive correction 93/42 / EEC implemented in Italy by Legislative Decree no. 46/97 amended with Legislative Decree no. 37 / 10.

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The following standards and/or other normative documents:

UNI EN ISO 13485-2012
UNI EN ISO 9001-2008

Nola, 2th September 2020

BIODIAGRAM S.r.l
CEO Domenico Maiello

BIODIAGRAM
CARTE DIAGRAMMATE
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