

## 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
PXXXXXXXXXXXXX/RXXXXXXXXXXXXX	CHART PAPERS FOR MEDICAL USE
SNC-UPPXXXXX	VIDEOPRINTER PAPER

### 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, in accordance with Annex IX of Directive 2007/47 / EC, Directive correction 93/42 / EEC;
- 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.

I

The following standards and/or other normative documents:

**UNI EN ISO 13485-2012**

**UNI EN ISO 9001-2008**

Nola, 29th September 2020

BIODIAGRAM S.r.l  
CEO Domenico Maiello



**BIODIAGRAM**  
CARTE DIAGRAMMATE  
Via Boscofangone (Area ASI Nola-Marigliano) 80035 NOLA (NA)  
Tel. 0818269364 - Fax 0818268752 - email: info@biodiagram.com

**BIODIAGRAM s.r.l.**

Via Bruno Buozzi, 1  
80040 San Sebastiano Al Vesuvio (NA), Italy  
Via Boscofangone, snc (Zona ASI Nola-Marigliano)  
80035 Nola (NA), Italy  
Tel.: +39. 081.826 93 64 Fax: +39. 081.826 87 52  
P.IVA/C.F./C.C.I.A.A.: IT 03526561216 - R.E.A.: NA 0608254  
www.biodiagram.com info@biodiagram.com

**Sede Legale:**

**Sede Oper. e Stabilimenti:**