

EU DECLARATION OF CONFORMITY

The undersigned RAYS S.p.A., registered in EUDAMED with Single Registration Number IT-MF-000009229, with registered office in Osimo (AN) in Via Francesco Crispi n. 26, Tax Code 01316780426 e VAT number no. 01316780426, manufacturer of Medical Devices:

NON-STERILE PLASTERS
Commercial Name “**BIO PAP**”
Class I Medical Device

Intended use: Medical device for fixing dressings, tubes, probes, and catheters.

ARTICLE CODE	Basic UDI-DI	RDM
PAP51NBSB	8034055915929	2203963
PAP01NBSB	8034055918838	2208765
PAP02NBSC	8057014183085	2203981
PAP03NBSC	8057014183092	2203974
PAP04NBSD	8032764159061	2203987
PAP05NBSD	8057014183108	2203976
PAP08NBSD	8051884681245	2204516
PAP37NBSC	8057014187823	2208767
PAP75NBSD	8051884686288	2443937

Declares, under its sole responsibility, that the medical devices covered by this declaration comply with the provisions of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 relating to medical devices, which amends Directive 2001/83/ EC, Regulation (EC) no. 178/2002 and Regulation (EC) no. 1223/2009 and which repeals Council Directives 90/385/EEC and 93/42/EEC and the Official Pharmacopoeia in force.

To this end, it guarantees the following:

1. The products in question are to be considered Medical Devices belonging to Class I according to rule 1 of chapter III of Annex VIII of Regulation (EU) 2017/745 of the European Parliament and of the Council;
2. to undertake to preserve and keep the product Technical File available, specified in point 8 of article 10 of Regulation (EU) 2017/745, for a period of at least ten years from the last date of placing the product on the market last batch produced;
3. that the medical device respects the general safety and performance requirements;
4. that the quality management system of the RAYS S.p.A. organization pursuant to the legislation EN ISO 13485:2016 has been certified by the Notified Body IMQ S.p.A. – Via Quintiliano, 43 – 20138 Milan.

Truly yours
Osimo, 09/01/2023

RAYS S.p.A.
Quality Department

RAYS Spa
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Cod. Fisc. e Part. IVA 01316780426