DECLARATION OF CONFORMITY

This declaration is issued under the sole responsibility of the manufacturer.

COMPANY ADDRESS	**PVS Spa** LEGALE SITE: Via Leonardo da vinci, 18 - 20051 Cassina de pecchi (Mi)
Unique registration number (art.31)	not available yet
DEVICE	FIXO SPLINT
DESCRIPTION	FIXO SPLINTPENCIL
CODE	STE120/P
BUDI-DI (UDI-DI di base)	80340280124F
INTENDED USE	Rigid splint for immobilization of the lower and upper limbs. The velcro closures allow a quick and safe fixing. They are washable and radiolucent.
RISK CLASS	I (Rule, 1 - Annex VIII)
CONFORMITY ASSESSMENT PROCEDURE	Annex II (technical documentation) Annex III (technical documentation on post-market surveillance)
DECLARATION	It declares under its own responsibility: • that the device meets the general safety and performance requirements set out in Annex I of EU regulation 2017/745 on medical devices and the applicable technical standards set out in the technical file. • that the device in question IS NOT A MEASURING INSTRUMENT; • that the device in question is sold in NO STERILE packaging; • that the devices in question are not intended for clinical investigations; • that the company has implemented and maintains a post-marketing surveillance procedure, in accordance with the requirements of Annex III; • that the device is produced and marketed by applying the company Quality System certified according to the UNI EN ISO 9001: 2015 standard; • that the company undertakes to keep and make available to the Competent Authority the technical documentation, specified in Annex II and III for a period of at least 10 years from the last date of manufacture of the product; • that the device in question complies with the requirements of EU regulation 2017/745 and that it is placed on the market with the CE marking, in accordance with the provisions of Article 20.

Cassina De Pecchi, 18/05/2021

VITTORIO PEREGO
PRESIDENTE DEL CONSIGLIO DI AMMINISTRAZIONE

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PVS SpA

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