

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	REFILL BOX ADHESIVE PLASTERS FOR BOLERO DISPENSER
DESCRIPTION	REFILL BOX ADHESIVE PLASTERS FOR BOLERO DISPENSER
PVS CODE	CER451
BUDI-DI (UDI-DI di base)	80340280154M
INTENDED USE	Medical device for dressing small wounds
RISK CLASS	I (Rule, 1 - Annex VIII)
CONFORMITY ASSESSMENT PROCEDURE	Annex II (technical documentation) Annex III (technical documentation on post-market surveillance)
DECLARATION	<p>It declares under its own responsibility:</p> <ul style="list-style-type: none"> • 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.

PVS SpA

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Reg.imprese MI n. 215184
R.E.A. MI n. 1103165

Cassina De Pecchi, 11/01/2022




IRENE PEREGO
GENERAL MANAGER



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PVS SpA

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