

DECLARATION OF CONFORMITY

Declaration in accordance with Regulation MDR 2017/745 art. 22 point 2

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	PREMIER KIT
DESCRIPTION	PREMIER KIT
CODE	CPS515
BUDI-DI (UDI-DI di base)	805638129
INTENDED USE	FIRS AID KIT
DECLARATION	<p>We declare under our own responsibility that :</p> <ul style="list-style-type: none"> • the medical devices contained comply with 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 and in accordance with MDD 93/42/ EEC. • The medical devices contained are CE marked according to MDD 93/42 / EEC and subsequent amendments and / or according to MDR 2017/745. • Medical devices comply with the requirements of MDD 93/42 / EEC and subsequent amendments. and / or MDR 2017/745 and can be classified in class I, Is, Ir, Im, IIa, IIb and / or III. • The medical devices contained can also be used individually. • The devices contained in the set can be produced by different manufacturers, which affix the CE marking according to the risk class. • The mutual compatibility of the devices was checked according to the manufacturers' instructions and the operation was carried out according to their instructions. • The complete system or kit has been packed and the relevant information has been provided to the users, containing the relevant instructions from the manufacturers. • The entire business is subject to adequate internal verification and control methods.

Cassina De Pecchi, 16/05/2022
Irene Perego
General Manager



PVS SpA

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