



DECLARATION OF CONFORMITY

PVS SpA located in Leonardo da Vinci, 18 street , 20051 Cassina De' Pecchi (Mi), Italy, as assembler of the following kit :

Description	PREMIER KIT
REF	CPS515
Basic UDI-DI	80340280114D SRN - IT - PR - 000050312

Composition :

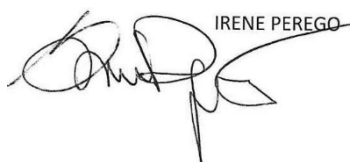
- 1 POVI IODINE 125 ml bottle
- 2 Pair of Sterile COPOLIM Gloves MD class Is
- 1 Sterile solution 250 ml MD class IIa
- 3 Sterile single gauze 18x40 MD class Is
- 1 pack cotton 20 gr. MD class I
- 1 Sterile tweezers 10 cm MD class Is
- 1 Case of 10 assorted plasters MD class I
- 1 spool of TNT plaster m 5x2.5 cm MD class I
- 1 elastic bandage m 4 x 10 cm MD class I
- 1 Lister scissors 14.5 cm MD class I
- 1 NITRILE DM tourniquet class I
- 1 Bag. HEALTH WASTE 180x250 mm
- 1 ICE PACK MD class IIa
- 1 TNT triangular cm.96x96x136 MD class I
- 1 40 x 60 DIN 13152-BR for burns MD class Is
- 3 Gauze compress cm10x10 sterile MD class Is

In compliance with Article 22 of REG. UE 2017/745, declares that :

- a) the mutual compatibility of the devices has been verified;
- b) is responsible for assembly, packaging and has provided users with the relevant information containing the relevant manufacturer's instructions
- (c) the activity of combining the devices into procedural kits has been subjected to adequate methods of internal control, verification and validation.
- d) the system incorporates both CE medical devices and non-medical devices.

Cassina De' Pecchi, 30.09.2025

LEGAL REPRESENTATIVE



IRENE PEREGO