

DECLARATION OF CONFORMITY

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

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	Description	102 M KIT	ĺ.
	REF	CPS499	
	Basic UDI-DI	80340280114D	

Composition:

1 Copy of Min Decree 388 dated 15.07.03

5 pairs of sterile gloves MD class Is

- 1 Mask with fluid protect visor MD class I
- 3 Bottles Sterile physiological solution 500 ml Md class IIa
- 2 Disinfectant bottles $500\ ml$ IODOPVIDONE with 10% iodine
- 10 envelopes of sterile gauze compresses 10×10 cm MD class Is
- 2 envelopes of sterile gauze compresses 18×40 cm MD class Is
- 2 sterile sheets cm 40×60 DIN 13152-BR MD class Is
- 2 sterile forceps MD class Is
- 1 pack of cotton wool MD class I
- 1 Tubular elastic bandage case MD class I
- 2 PLASTOSAN 10 assorted plasters MD class I
- 2 Rolls of adhesive plaster m 5×2,5 cm MD class I
- 1 Pair of bandage cutters 14.5 cm DIN 58279 MD class I
- 3 Tourniquets Md class I
- 2 ICE PACK instant disposable ice MD class IIa
- 2 Bags for medical waste
- 1 digital clinical thermometer MD class Im
- 1 GIMA sphygmomanometer MD class IIa

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.

LEGAL REPRESENTATIVE

IRENE PEREGO-

Cassina De Pecchi, 31/08/23