



## 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	103/M ALL.2 KIT
REF	CPS522
Basic UDI-DI	80340280114D

Composition :

- 1 Copy of Min Decree 388 dated 15.07.03
- 2 pairs of sterile gloves MD class Is
- 1 Disinfectant bottle 125 ml IODOPVIDONE with 10% iodine
- 1 sterile physiological solution 250 ml MD class Is
- 3 bags of sterile gauze compresses 18×40 cm MD class Is
- 3 bags of sterile gauze compresses 10×10 cm MD class Is
- 2 packs of cotton wool MD class I
- 1 PLASTOSAN 20 assorted plasters MD class I
- 1 Sterile forceps MD class Is
- 1 Roll of adhesive plaster m 5×2.5 cm MD class I
- 2 Gauze bandage m 3.5×10 cm MD class I
- 1 pair of bandage cutters cm 14,5 DIN 58279 MD class I
- 1 tourniquet MD class I
- 1 ICE PACK instant disposable ice MD class IIa
- 1 Bag for sanitary waste 250×350 mm
- 1 Triangular non-woven sheet 96x96x136 cm MD class I
- 1 Gold/Silver Isothermal Blanket 160x210cm MD class I
- 1 PIC 3 box containing: 3 liquid soap sachets, 3 disinfectant wipe sachets, 2 ammonia wipe sachets
- 1 Preparation 3.5 g GEL FOR BURNS sterile MD class IIb
- 1 sterile pad 80×100 mm DIN 13151 M MD class class Is
- 2 Sterile sheet 40×60 cm DIN 13152-BR MD class Is
- 1 hand disinfectant gel 100 ml

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, 14/09/22**



