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	805 M GIMA KIT
REF	CPS219
Basic UDI-DI	80340280114D

Composition :

3 pack cotton 50 gr. bag MD class I

1 PIC disinfectant bottle 250 ml

1 standard hydrogen peroxide 3% ml.250

1 assorted plasters 8 sizes MD class I

1 pack of 100 PLASTOSAN plasters 7x2 cm MD class I

3 nitrile tourniquet MD class I

1 lister scissors 14.5 cm MD class I

2 spool of TNT plaster m 5x2.5 cm MD class I

1 PIC 3 Case rescue 8 saves. ass.

10 RAYS bag 25 sterile gauzes 10x10 MD class Is

6 single sterile 18x40 gauze MD class Is

4 TNT triangular cloth 96x96x136 cm MD class I

1 elastic bandage 7 cm with bandage holder MD class I

2 40 x 60 gauze DIN 13152-BR for burns MD class Is

2 pack of 10 3-ply paper handkerchiefs

2 ice pack instant ice MD class IIa

1 gold/silver isothermal blanket. 160x210 cm MD class I

1 emocontrol anti-hemorrhagic bandage MD class I

1 PLASTONET tubular bandage 2 sizes MD class I

5 medical waste bag180x250 mm

1 mask + splash guard MD class I

1 PVS digital thermometer MD class Im

2 sterile tweezers 10 cm MD class Is

3 saline sterile solution 500 ml BOTTLE MD class IIa

2 POVI IODINE 500 ml bottle

5 pair Sterile copolymer gloves one size MD class Is

3 BURNSHIELD 3.5 g sterile burns gel MD class IIb

4 elastic bandage m4 x 6cm DIN 61634 MD class I

2 elastic bandage m4 x 8cm DIN 61634 MD class I

2 elastic bandage m 4 x 10 cm MD class I

1 helical mouth MD class I

1 mouth to mouth resuscitator MD class I

1 GIMA digital sphygmomanometer MD class Im

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, 03/05/24