



DECLARATION OF CONFORMITY

PVS SpA located in Leonardo da Vinci, 18 street , 20060 Cassina De' Pecchi (Mi), Italy, as assembler of the following kit :

Description	TRIX KIT
REF	CPS011
UDI-DI	80563832D

Composition :

- 2 sterile gauze pads cm 18x40 MD class Is
- 1 pair of scissors cm 10 MD class I
- 1 plastic tweezers MD class I
- 1 sterile bandage tnt cm 40x60 MD class Is
- 1 VENTO mouth to mouth airway MD class IIa
- 1 pack of 10 adhesive plasters MD class I
- 1 tissue pack 10 pcs
- 3 disinfectant wipes;
- 1 elastic bandage 4x10 cm MD class I
- 1 adhesive dressing cm 10x6 MD class I
- 1 adhesive plaster roll m 5 x 1,25 cm MD class I
- 1 pair of sterile gloves. 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, 28/10/22

LEGAL REPRESENTATIVE
IRENE PEREGO
