



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	REFILL PACK DM388
REF	PDM090
Basic UDI-DI	80340280114D SRN- IT - PR- 000050312

Composition :

- 2 Pairs of sterile gloves; MD CLASS 1s
- 1 Disinfectant 125 ml IODOPOVIDONE ;
- 1 saline solution 250 ml; MD CLASS 2a
- 1 Sterile compressed gauze bag 18x40 cm; MD CLASS 1s
- 3 Sterile compressed gauze 10x10 cm; MD CLASS 1s
- 1 Sterile forceps; MD CLASS 1s
- 1 pack of cotton wool; MD CLASS 1
- 1 PLASTOSAN 10 assorted plasters; MD CLASS 1
- 1 Roll of adhesive plaster m 5x2.5 cm; MD CLASS 1
- 1 Gauze bandage m 3.5x10cm; MD CLASS 1
- 1 Pair of scissors 10 cm FOR078; MD CLASS 1
- 1 Tourniquet; MD CLASS 1
- 1 ICE PACK ; MD CLASS 2a
- 1 Bag for medical waste 250x350 mm;

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, 30/09/25

