



## 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 DM 388 ALL.1 WITHOUT SPHYGMOMANOMETER |
| REF          | PDM091                                            |
| Basic UDI-DI | 80340280114D SRN - IT - PR - 000050312            |

Composition :

- 1 Ministerial decret copy 388 of the 15/07/03
  - 5 Pair of sterile gloves MD class Is
  - 1 Safety mask with eye protection visor MD class I
  - 3 Saline solution 500 ml CE MD class IIA
  - 2 Jodopovidone Disinfectant solution at 10% 500 ml
  - 10 Sterile gauze 10x10 cm sachets MD class Is
  - 2 Sterile gauze 18x40 cm sachets MD class Is
  - 2 Sterile bandage cm 40x60 DIN13152BR MD class Is
  - 2 Sterile tweezers MD class Is
  - 1 Pack of cotton DM class I
  - 1 Pack of net elastic bandage DM class I
  - 2 Plastosan 10 assorted dressings DM class I
  - 2 Adhesive plaster m 5 x 2,5 cm DM class I
  - 1 LISTER pair of scissors 14,5 cm DIN58279 DM class I
  - 3 Tourniquet DM class I
  - 2 Instant ICE pack DM class Ila
  - 2 Sanitary bag
  - 1 Clinical digital thermometer CE DM class Ila
- 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**

**Cassina De Pecchi, 30/09/25**

 IRENE PEREGO

