

DECLARATION OF CONFORMITY

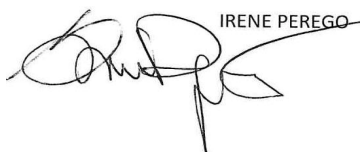
PVS SpA located in Leonardo da Vinci, 18 street , 20060 Cassina De' Pecchi (Mi), Italy, as assembler of the following kit :

| | |
|-------------|---------------------------|
| Description | MULTISAN KIT ALL.1 DM 388 |
| REF | CPS200 |
| UDI-DI | 80340280114D |

Composition :

- 1 Copy DM 388 of 15/07/03,
 - 5 Pairs of sterile gloves, MD class Is
 - 1 Mask with visor , MD class I
 - 3 Bottles of sterile saline solution 500 ml CE, MD class IIa
 - 2 Bottles of disinfectant 500 ml iodopovidone 10% iodine PMC,
 - 10 bags of sterile gauze compressed 10x10 cm, MD class Is
 - 2 Bags of sterile compressed gauze 18x40 cm, MD class Is
 - 2 Sterile sheets cm 40x60 DIN 13152-BR, MD class Is
 - 2 Sterile tweezers MD class Is
 - 1 Pack of cotton wool, MD class I
 - 1 Packs of 10 assorted patches, MD class I
 - 2 Spools adhesive patch m 5x2,5 cm, MD class I
 - 1 Pair of scissors cutting bandages 14.5 cm DIN MD class I
 - 3 Tourniquets MD class I
 - 2 Instant Ice Pack MD class IIa
 - 2 Bags for medical waste
 - 1 Clinical thermometer MD class IIa
 - 1 Personal Sphygmomanometer with phonendoscope. 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, 15/11/2022