



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	BURN KIT
REF	CPS359
Basic UDI-DI	80340280114D SRN-IT-PR-000050312

Content:

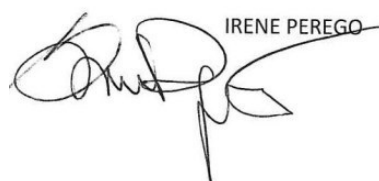
- 10 anti-burn gel sachets 3.5 gr.; MD class IIb
- 4 sterile anti-burn gauzes 10×10 cm; MD class IIb
- 1 lister scissors 14.5 cm; MD class I
- 1 sterile saline solution 100 ml; MD class IIa
- 1 disposable sterile forceps; MD class Is
- 1 spooled plaster m 5×2.5 cm; MD class I
- 2 sterile TNT drapes 40×60 cm; MD class Is
- 3 bandage with non-stick pad 100 x 120 mm; MD class Is
- 1 anti-burn hydrogel bottle 50 ml; MD class IIb
- 1 skin-coloured self-adhering plaster 6×100 cm; MD class I
- 4 envelopes of 1 sterile gauze compress 10×10 cm 8 layers; MD class Is
- 2 pairs 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, 30.09.2025

LEGAL REPRESENTATIVE



IRENE PEREGO

