



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	PINOCCHIO HELICOIDAL MOUTH AND VENTO KIT
REF	APR100K
Basic UDI-DI	80340280114D

Composition :

1empty case
1VENTO mouth mouth MD
1helical mouth opener MD

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, 22/06/23

LEGAL REPRESENTATIVE

IRENE PEREGO