

SISTEMI E PRODOTTI PER IL PRONTO SOCCORSO E LA RIANIMAZIONE

DECLARATION OF CONFORMITY

This declaration is issued under the sole responsibility of the manufacturer

COMPANY'S ADDRESS REGISTRED OFFICE: Via Leonardo da Vinci, 18 – 20060 Cassina De Pecchi (MI)

Sole Registration number (art. 31) not yet available

DEVICE	TONGUE CLAMP
DESCRIPTION	TONGUE CLAMP
CODE	PIN201
BUDI-DI (DI base)	80340280154M
INTENDED USE	Device used in case of emergency, when the patient is unconscious and there is a danger that the tongue can cause the suffocation.
RISK CLASS	CLASS 1 ( Rule, 1 – Annex VIII)
CONFORMITY ASSESSMENT PROCEDURE	Annex II ( technical documentation) Annex III ( technical documentation on post-market surveillance)
DECLARATION	We declare under our own responsibility

- that the device meets with the general safety requirements and performance set out in Annex I of the regulation UE 2017/745 on medical devices and the applicable technical standards listed in the technical file.
- that the device IS NOT A MEASURING INSTRUMENT
- that the device is marketed in NON STERILE packaging
- that the devices are not intended for clinical investigations
- that the company has implemented and mantains a post market surveillance procedure as prescribed in Annex III

**PVS SpA**

20060 CASSINA DE PECCHI (MI)  
Via Leonardo da Vinci,18

+39 029160011  
+39 0291600310  
+39 0291600149

Email: [info@pvs-spa.it](mailto:info@pvs-spa.it) Web: [www.pvs-spa.it](http://www.pvs-spa.it)

cod.fiscale part.IVA/VAT IT 06532250153  
cap.soc. Euro 619.748,28 i.v.  
Reg.imprese MI n. 215184  
R.E.A. MI n. 1103165

- that the device is produced and marketed by applying the company quality system certified according the UNI EN ISO 9001:2015 standard
- that the company undertakes to keep and make available the technical documentation specified in annexes II and III to the competent authority for a period of at least 10 years from the last date of manufacture of the product
- that the device complies with the UE 2017/745 regulation and that is placed on the market with the CE marking according with the Article 20

Cassina de Pecchi, June the 10<sup>th</sup> 2022

PVS SPA

IRENE PEREGO

MANAGING DIRECTOR