PVS FIRST AID

CERTIFICAZIONE DI SISTEMA QUALITÀ DNV·GL ISO 13485

SISTEMI E PRODOTTI PER IL PRONTO SOCCORSO E LA RIANIMAZIONE

DECLARATION OF CONFORMITY

This declaration is issued under the sole responsability 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 avaiable

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

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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 avaiable 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 10th 2022

PVS SPA

IRENE PEREGO

MANAGING DIRECTOR