



super-tex srl

INDUSTRIA ARTICOLI PUERICULTURA International Baby - Products Program
PRODUZIONE SANITARI IN GOMMA, MEDICALI, PARAFARMACEUTICI, RESINE E DIVERSI

DECLARATION OF CONFORMITY

This declaration is issued under the sole responsibility of the manufacturer

COMPANY ADDRESS	SUPER-TEX Srl LEGAL AND OPERATIONAL HEADQUARTERS: Via San Giuliano, snc - 03039 Sora (FR)
Unique Registration Number (art. 31)	Not available yet
DEVICE	TOURNIQUET
DESCRIPTION	NON-STERILE DISPOSABLE LATEX TUBULAR TOURNIQUET
CODE	204
LOT	
BUDI-DI (BASIC UDI)	802359901PX
INTENDED USE	Mechanical barrier for compressing blood vessels during venipuncture or as a mechanical barrier upstream of wounds to stop bleeding.
RISK CLASS	I (Rule, 1 – Annex VIII)
CONFORMITY ASSESSMENT PROCEDURE	Annex II (Technical documentation) Annex III (Technical documentation on postmarket surveillance)
DECLARATION	Declare itself under its own responsibility: <ul style="list-style-type: none">● that the device satisfies the general safety and performance requirement set out in Annex I of the EU regulation 2017/745 on medical devices and the applicable technical standard reported in technical file.● that the device in question IS NOT A MEASURING INSTRUMENT;● that the device in question is marketed in NON STERILE packaging;● that the device in question are not intended for clinical investigation;● that the company has implemented and maintains a post market surveillance procedure as required by Annex III;● that the device is produced and marketed by applying the company Quality System certified according to the UNI EN ISO 9001:2015;● that the company undertakes to keep an make available to the Competent Authority the technical documentation specified in Annexes II and III, for a period of at least 10 years from the last date of the product;● that the device in question complies with the provisions of EU regulation 2017/745 and that it is placed on the market with the CE marking in accordance with the provisional of Article 20.

Place and date of issue:

Sora (FR),

RSCG

Dott. Angelo Carlesimo

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