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 responsability of the manufacturer

COMPANY ADRESS	**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 venipunctureor 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 responsability: ● 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 previsions 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.

Palce and date of issue:

Sora (FR),

RSGQ

Dott. Angelo Carlesimo

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