Megapharma Ospedaliera s.r.l. unipersonale

Capitale Sociale € 50.000,00 · Reg. Imp. TV 25056 · R.E.A. 185002 · C.F. e Part. IVA 02032400265
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UE DECLARATION OF CONFORMITY

This UE Declaration of Conformity is released under the Manufacturer responsibility only, the document is in conformity with what established in the enclosure IV of the UE Regulation 2017/745 about Medical Devices.

Manufacturer		Megapharma Ospedaliera s.r.l. unipersonale	
Unique registration number		APP000007701 (procedure's ID)	
headquarters		Via Asolana n. 26/b - loc. Crespano 31017 Pieve del Grappa (TV) - Italia	
Point of contact		tel. +39 0423 538746 fax +39 0423 538748 e-mail info@megapharma.it e-mail PEC megapharma@pcert.it	
Device's name		**Finger and limb splint**	
Device's code		04SDxxxx	
Destination of use		Protection and immobilization of the interested area (fracture)	
Basic UDI-DI (GMN)		80569779804S00AK	
Risk's class	**I** (no sterilized)	*Classification regulation (Enclosure VIII)*	1
CS (Common Specifications) used		-	
Armonized rules applied		UNI CEI EN ISO 13485 - UNI CEI EN ISO 14971 - UNI CEI EN ISO 15223-1 - UNI EN 1041 - ISO 10993-1	

The manufacturer Megapharma Ospedaliera claims, under its own responsibility, that the Medical Device in question, respects the UE Regulation 2017/745 about Medical Devices and that it satisfies the general safety and performance requirements of the enclosure I of the overmentioned Regulation.

The manufacturer claims too that its Quality Management System is certified in conformity with the Regulation UNI CEI EN ISO 13485.

Pieve del Grappa, 13rd July 2021

The President
(Antonio Petranich)