

EC DECLARATION OF CONFORMITY

Manufacturer

FORA GRUP SAVUNMA TEKNOLOJİLERİ VE DAN. TİC. LTD. ŞTİ.

Address

MUSTAFA KEMAL MAH. 2141. CD. MOLMED PLAZA 15/10 ÇANKAYA/ANKARA/TURKEY

Branch (Factory): ŞEHİT OSMAN AVCI MAH. 1404. CD. NO.4 ETİMESGUT/ANKARA/TURKEY

Product: FR19® (UPPER AND LOWER EXTREMITIES TOURNIQUET)

Catalog/Ref. No: FRT-EKS01 BL

Product Description: Bleeding control in lower and upper extremity injuries.

UDI-DI: 868216933902LR

Classification: CLASS I

GMDN Code: 14074

Conformity Assessment Procedure: ANNEX IV (II & III) Declaration Of Conformity

**Related Standards: EN ISO 14971:2020, EN ISO 15223-1:2016,
EN ISO 1041:2008+A1:2014, EN ISO 13485:2016**

As FORA GROUP, we declare under our sole responsibility that the device within the scope of this declaration comply with the Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices and the requirements specified in the Regulation for these devices are fulfilled.

*Mustafa Kemal Mah. 2141 Cd.
Molmed Plaza 15/10
Çankaya/ANKARA/TURKEY*

November 10, 2021

Place and date of issue

**FORA GRUP SAVUNMA TEKNOLOJİLERİ
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