

DECLARATION OF CONFORMITY

Section No	TD-01/5.3
Rev. Date	01.10.2024
Rev. No	00
Page No	1 / 2

Company Name : Avrasyamed Medikal Tıbbi Cihazlar Ve Ürünler Pazarlama Sanayi Ve Dış Ticaret Limited Şirketi

Address : Cihangir Mh. Güvercin Cd. No: 4 İç Kapı No: 144 Avcılar

City : İstanbul

Country : TÜRKİYE

Tel : +90 212 590 4240

SRN : TR-MF-000040217

Product Name : Tourniquet Cuff

Model : Model list attached

Brand Name : Medione

Class and Rule : Class I Rule I

EMDN : Z12139006

Basic UDI : 8682754922010256

Intended Use : It is used for clinical venous blood drawing, hemostatic tying of venipuncture, and hemostasis treatment when treating limb bleeding at accident sites and battlefields; or it can be used to expel blood from limbs during limb surgery.

Conformity Assessment Procedure: Annex IV

Applicable Standards: EN ISO 13485:2016, EN ISO 15223-1:2021, EN ISO 14971:2019, EN ISO 20417:2021, EN 62366-1:2015/A1:2020, EN ISO 10993-1:2020.

We herewith declare on our own responsibility that the above mentioned meet the provisions of the Council Directive MDR 2017/745 for Medical Device Directive.

City, Date : İstanbul, 01.10.2024

Name : Deniz Birinci

Position : General Manager

Signature



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Section No	TD-01/5.3
Rev. Date	01.10.2024
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Page No	2 / 2

Annex I: Product List

Product Code	Description
Reusable Single Hose Cuffs	
AVR-CUFF S008	8" Reusable Single Cuff 8"L x 2"W ONE CHAMBER
AVR-CUFF S012	12" Reusable Single Cuff 12"L x 3"W ONE CHAMBER
AVR-CUFF S015	15" Reusable Single Cuff 15"L x 4"W ONE CHAMBER
AVR-CUFF S018	18" Reusable Single Cuff 18"L x 4"W ONE CHAMBER
AVR-CUFF S024	24" Reusable Single Cuff 24"L x 4"W ONE CHAMBER
AVR-CUFF S030	30" Reusable Single Cuff 30"L x 5"W ONE CHAMBER
AVR-CUFF S034	34" Reusable Single Cuff 34"L x 5"W ONE CHAMBER
AVR-CUFF S038	38" Reusable Single Cuff 38"L x 5"W ONE CHAMBER
AVR-CUFF S042	42" Reusable Single Cuff 44"L x 6"W ONE CHAMBER
AVR-CUFF S044	44" Reusable Single Cuff 44"L x 6"W ONE CHAMBER
Reusable Double Chamber Double Hose IVRA Cuff	
AVR-CUFF 2XD014	14" Reusable Double Cuff 14"L x 4"W DUAL CHAMBER
AVR-CUFF 2XD020	20" Reusable Double Cuff 20"L x 6"W DUAL CHAMBER
AVR-CUFF 2XD026	26" Reusable Double Cuff 26"L x 6"W DUAL CHAMBER
AVR-H003	Extension Hose 5m

Signature

City, Date : İstanbul, 01.10.2024

Name : Deniz Birinci

Position : General Manager

AVRASYAMED MEDİKAL
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