

DECLARATION OF CONFORMITY

Section No	TD-01/5.1
Rev. Date	06.12.2024
Rev. No	06
Page No	1 / 1

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

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

City : İstanbul

Country : TÜRKİYE

Tel : +90 212 590 4240

Product Name	Model	Brand	GMDN	Class and Rule
Automatic Tourniquet Device	TRQ-2020 TRQ-2022 TRQ-2024	Medione	14074	Class 2a Rule 9

Conformity Assessment Procedure: Annex V

Applicable Standards: EN ISO 13485:2016, EN ISO 15223-1:2021, EN ISO 14971:2019, EN ISO 20417:2021, EN 60601-1:2006/A2:2021, EN 60601-1-2:2015/A1:2021, EN 62366-1:2015/A1:2020, EN 60601-1-6:2010/A2:2021, EN 62304:2006/A1:2015, EN 60601-1-8:2007/A2:2021.

We herewith declare on our own responsibility that the above mentioned meet the provisions of the Council Directive 93/42/EEC with amended directive 2007/47/EC for Medical Device Directive.

Notified Body : KIWA Belgelendirme Hizmetleri A.Ş.

NB Address : İTOSB 9. Cadde No:15 Tepeören Tuzla İstanbul Türkiye

NB Identification Number : 1984

EC Certificate Number : 1984-MDD-20-650

EC Certificate Expiry Date : 31 Dec 2028

City, Date : İstanbul, 10.06.2024

Name : Deniz Birinci

Position : General Manager

Signature

AVRASYAMED MEDİKAL
Tıbbi Cihazlar ve Ürünler Pazarlama Sanayi ve Dış Tic. Ltd. Şti.
Cihangir Mh. Güvercin Cd. No: 144 İç Kapı No: 144 Avcılar / İstanbul
Tic. Sic. No: 274200 / 42 40 41 Fik. Sic. No: 274200 / 42 40 41
Tic. Sic. No: 274200 / 42 40 41 Fik. Sic. No: 274200 / 42 40 41