



# EC Declaration of Conformity

according to the Directive of 98/79/EC

**Manufacturer** Hemonart Medikal Sistemler Sanayi Ticaret A.Ş.

**Address** Alacaatlı Mah., Şehit Hayrettin Eren Cad., No:24/AF,06810 Çankaya/Ankara  
TURKEY

**EC Representative** Eucerep B.V.  
**Address** Roald Dahllaan 33 , 5629MC , Eindhoven , The Netherlands

**We, the manufacturer, declare under our sole responsibility that**

**The medical device(s)** Hemonart CompactOne 9 ACT analyzer  
BlacT ACT test tube, Ref:ACT3017

**Classification** Others in vitro diagnostic device (IVD)

**is/are in conformity with the relevant provisions and requirements of Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.**

**Conformity assessment** Module A (EC Declaration of Conformity) (Annex III, except point 6)  
**Procedure**

We declare that the use of the device(s) under appropriate conditions as described in product instructions of use will not compromise the health or safety of the patient, the user or other involved person. We will ensure the institute and to keep up date a quality system which enables us to review experiences gained from the device(s) in the post-production phase and to implement the necessary corrective actions.

**Signed on:** 02.05.2022

**Place:** Ankara / Turkey

**Signature of General Manager**

**Abdullah DEMİRÖRS**



APOSTILLE

( Convention de La Haye du 5 Octobre 1961 )

1. Ülke/Country/Pays/Staat TÜRKİYE - LA TURQUIE

İşbu resmi belge/This public document/Le présent acte public/Dieses zeugnis wurde

2. ERTUNGA GÜLDİRİM tarafından imzalanmıştır./Has been signed by/a été signé par/durch ...  
unterschrieben

3. İmzalayanın sıfatı Ticari Belgelendirme Müdürlüğü Personeli'dir./Acting in the capacity  
of/Agissant en qualité de/Titel des Unterzeichneten

4. ANKARA TİCARET ODASI 'nin mühür/damgasını taşımaktadır-bears the seal/stamp of-/est  
revétu du sceau/timbre de-trägt Siegel/Stempel von

TASDİK / CERTIFIED / ATTESTE / BEGLAUBIGUNG:

5. Çankaya Kaymakamlığı' da/at/à/in

6. 23.08.2023 günü/the/le/Am

7. Şef Ayşe Gül AS tarafından/by/par/durch den/die

8. No : 200044 ile tasdik edilmiştir./No:/sous No:/unter Nr.

9. Mühür - Damga/Seal-stamp/Sceau-  
timbre/Siegel-Stempel

10. İmza/Signature/Signature/Unterschrift:

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ANKARA CHAMBER OF COMMERCE  
Ertunga GÜLDİRİM  
Commercial Certification Directorate  
Expert  
p.p.-Secretary General



23 AUG 2023