



DECLARATION OF CONFORMITY

BIOTA GRUP SAGLIK SISTEMLERI SAN. VE TIC. LTD. STI.

Address : Izzetpasa Mah. Vefa Poyraz Cad.
No:5/5, 34387-Sisli
Istanbul/Turkey
Phone : +90 212 2485264
Fax : +90 212 2912865
E-mail : Biota@biota.com.tr

We hereby declare that the below mentioned products meet provisions of the Council Directive 98/79/EC Invitro Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

Description Of The Product : Hematology Analysers And Reagents

Product Brand : VABIO

Product Type/Model : VABIO560 Auto Hematology Analyzer
Including reagents as following:
VA-560D DILUENT
VA-560LH LH LYSE
VA-560L1 LYSE1
VA-560L2 LYSE2

Classification : Others, according to Annex III of IVD 98/79/EC

General Applicable Directives

Invitro Diagnostic Directive council directive 98/79/EC of October 1998 concerning in vitro diagnostic instruments (IVD 98/79/EC)

Standards

All applicable harmonized standards published in the official journal of the European Communities:
EN13612:2002; EN ISO 13485, EN 61010-1:20010; EN61010-2-101:2002; EN61326-1:2013; EN61326-2-6:2013; EN62304:2008; EN62366:2008; EN13640:2002

Date Of Issue : 15.10.2015 (Revision)

Signature :


BIOTA GRUP SAGLIK SISTEMLERI SAN. TIC. LTD. STI.
Izzetpasa Mah. Vefa Poyraz Cad. No:5/5 Sisli / ISTANBUL
Tel: 0 (212) 248 52 64 - Faks: 0 (212) 291 28 65
Kocithane V.D. V.No: 176 032 19970 - www.biota.com.tr
Mersis No.: 0176032199700016 - Tic. Sic. No: 538734

Name : Volkan Aghasi
Position : CEO