



DECLARATION OF CONFORMITY

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

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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 : VABIO360 Auto Hematology Analyzer
Including reagents as following:
VA-360D DILUENT
VA-360L LYSE
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

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Signature :


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