



DECLARATION OF CONFORMITY



Manufacturer: Pipar Medikal ve Sağlık Hizm. San. Tic. A.Ş

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Product name: Pipette tips, microcentrifuge tubes, falcon tubes, assay tubes, urine containers, stool collection containers, sample cups, tissue embedding cassettes, conical centrifuge tubes

Classification: Low risk group Annex of the IVD

We hereby declare that the above mentioned products meet the provisions of the Council Directive 98/76/EC in vitro medical Devices. All supporting documentation is retained under the promises of manufacturer.

General Applicable Directives: In vitro directive council directive 98/79/EC of October 1998 concerning in vitro diagnostic instruments (IVD 98/79/EC)

Standards to which conformity is declared:

EN 591:2001: Instructions for use in vitro diagnostic instruments for professional use.

EN 14971:2000 : Application of risk management to medical devices

EN 1658:1996: Requirements for marking of in vitro diagnostic instruments

Date of declaration: JUNE 17, 2014

Signed by : IDRIS MEHMETOGLU

Position: General Director

Signature:


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