

EC Declaration of Conformity

Köroğlu Medikal Tıbbi Malzemeleri Kozmetik İthalat İhracat San. Ve Tic. Ltd.
Şti.

1776/23 Sok. No:4/A Mevlana Mah. Bornova İzmir - Turkey

We declare under our sole responsibility that the in vitro diagnostic device:

Tradenames

Laboquick / Certain / Surelab

Products and Models

HBsAg Cassette Rapid Test Device

HBsAg Strip Rapid Test Device

meets all the provisions of the directive 98/79/EC on in vitro diagnostic medical devices which apply to it

This declaration is according to Annex IV of the Directive and the products mentioned are at Annex II List A Class

Authorized Representative:

Labex Engineering

Office 206 J&L Center Liubliana Str. 46 1618

Sofia - Bulgaria

List of Standards Applied

EN ISO 13485: 2012, EN ISO 14971:2012, EN 13975: 2003, EN ISO 18113-2:2011, EN 13612/AC: 2002-12, EN ISO 17511: 2003, EN ISO 15193: 2009, EN ISO 15194: 2009, EN ISO 23640:2013, EN 13641: 2002, EN ISO 15223-1: 2012

Detailed brand information and first place date, please refer to CE Product List.

Signed this on 15 th December 2013
in Izmir - Turkey

EC Certificate of Conformity No: 2014 / 02

Company Address: 1776/23 Sok. No: 4/A Mevlana Mah. Bornova – Izmir

Bektaş Erdur



Serkan Erdur

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