

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:

Trade Names

Laboquick / Certain / Surelab

Products and Models

Fecal Occult Blood Cassette Rapid Test Device

Fecal Occult Blood 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 III of the Directive

List of Standards Applied

EN ISO 13485: 2016, EN ISO 9001:2015, 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 September 2017
in İzmir - Turkey

EC Declaration of Conformity No: 2017 / 21

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

Serkan Erdur

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