

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 Izmir - Turkey

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

Trade Names

Laboquick / Certain / Surelab

Products and Models

Anti - Syphilis Cassette Rapid Test Device

Anti – Syphilis 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 III

Authorized Representative:

Labex Engineering

Office 206 J&L Center Liubliana Str. 46 1618

Sofia - Bulgaria

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

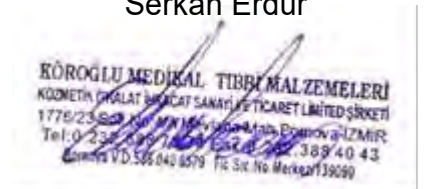
Detailed brand information and first place date, please refer to CE Product List.

Signed this on 15 th September 2017
in Izmir - Turkey

EC Certificate of Conformity No: 2017 / 01

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

Serkan Erdur



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 Izmir - Turkey

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

Trade Names

Laboquick / Certain / Surelab

Products and Models

Helicobacter Pylori Antigen Cassette Rapid Test Device

Helicobacter Pylori Antigen 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 III

Authorized Representative:

Labex Engineering

Office 206 J&L Center Liubliana Str. 46 1618

Sofia - Bulgaria

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

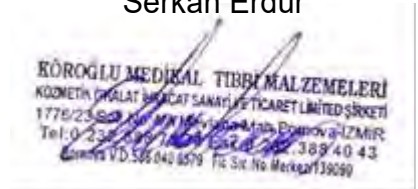
Detailed brand information and first place date, please refer to CE Product List.

Signed this on 15 th September 2017
in Izmir - Turkey

EC Certificate of Conformity No: 2017 / 02

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

Serkan Erdur



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

Helicobacter Pylori Antibody Cassette Rapid Test Device

Helicobacter Pylori Antibody 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 III

Authorized Representative:

Labex Engineering

Office 206 J&L Center Liubliana Str. 46 1618

Sofia - Bulgaria

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

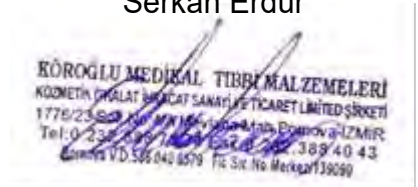
Detailed brand information and first place date, please refer to CE Product List.

Signed this on 15 th September 2017
in İzmir - Turkey

EC Certificate of Conformity No: 2017 / 03

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

Serkan Erdur



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 Izmir - Turkey

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

Trade Names

Laboquick / Certain / Surelab

Products and Models

Giardia Lamblia Antigen Cassette Rapid Test Device

Giardia Lamblia Antigen 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 III

Authorized Representative:

Labex Engineering

Office 206 J&L Center Liubliana Str. 46 1618

Sofia - Bulgaria

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

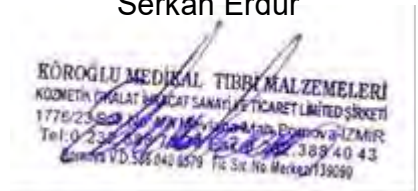
Detailed brand information and first place date, please refer to CE Product List.

Signed this on 15 th September 2017
in Izmir - Turkey

EC Certificate of Conformity No: 2017 / 04

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

Serkan Erdur



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

10 Parameter Urine Analysis Strip Test

11 Parameter Urine Analysis Strip Test

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 III

Authorized Representative:

Labex Engineering

Office 206 J&L Center Liubliana Str. 46 1618

Sofia - Bulgaria

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

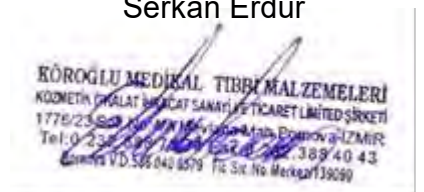
Detailed brand information and first place date, please refer to CE Product List.

Signed this on 15 th September 2017
in İzmir - Turkey

EC Certificate of Conformity No: 2017 / 05

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

Serkan Erdur



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

Candida Albicans Antigen Cassette Rapid Test Device

Candida Albicans Antigen 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 III

Authorized Representative:

Labex Engineering

Office 206 J&L Center Liubliana Str. 46 1618

Sofia - Bulgaria

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

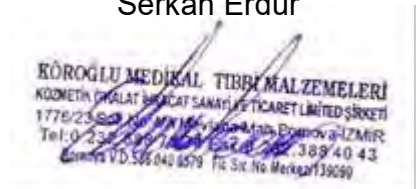
Detailed brand information and first place date, please refer to CE Product List.

Signed this on 15 th September 2017
in İzmir - Turkey

EC Certificate of Conformity No: 2017 / 06

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

Serkan Erdur



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

Adenovirus Antigen Cassette Rapid Test Device

Adenovirus Antigen 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 III

Authorized Representative:

Labex Engineering

Office 206 J&L Center Liubliana Str. 46 1618

Sofia - Bulgaria

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

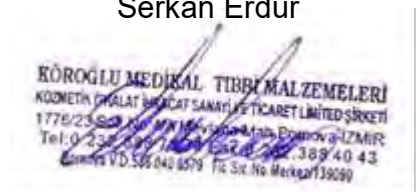
Detailed brand information and first place date, please refer to CE Product List.

Signed this on 15 th September 2017
in İzmir - Turkey

EC Certificate of Conformity No: 2017 / 07

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

Serkan Erdur



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

Trichomonas Vaginalis Antigen Cassette Rapid Test Device

Trichomonas Vaginalis Antigen 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 III

Authorized Representative:

Labex Engineering

Office 206 J&L Center Liubliana Str. 46 1618

Sofia - Bulgaria

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

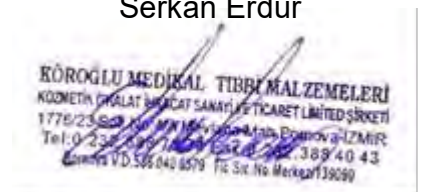
Detailed brand information and first place date, please refer to CE Product List.

Signed this on 15 th September 2017
in İzmir - Turkey

EC Certificate of Conformity No: 2017 / 08

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

Serkan Erdur



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

Rotavirus Antigen Cassette Rapid Test Device

Rotavirus Antigen 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 III

Authorized Representative:

Labex Engineering

Office 206 J&L Center Liubliana Str. 46 1618

Sofia - Bulgaria

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

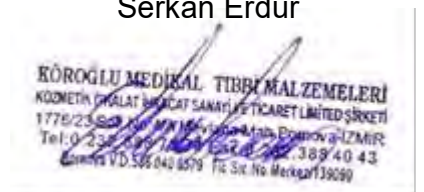
Detailed brand information and first place date, please refer to CE Product List.

Signed this on 15 th September 2017
in İzmir - Turkey

EC Certificate of Conformity No: 2017 / 09

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

Serkan Erdur



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

Rotavirus – Adenovirus Combo Antigen Cassette Rapid Test Device

Rotavirus – Adenovirus Combo 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 III

Authorized Representative:

Labex Engineering

Office 206 J&L Center Liubliana Str. 46 1618

Sofia - Bulgaria

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 Certificate of Conformity No: 2017 / 10

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

Serkan Erdur



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 Izmir - Turkey

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

Trade Names

Laboquick / Certain / Surelab

Products and Models

Troponin I Cassette Rapid Test Device

Troponin I 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 III

Authorized Representative:

Labex Engineering

Office 206 J&L Center Liubliana Str. 46 1618

Sofia - Bulgaria

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

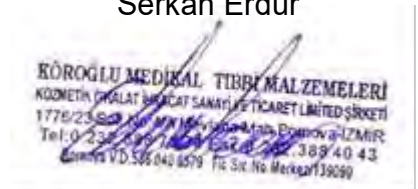
Detailed brand information and first place date, please refer to CE Product List.

Signed this on 15 th September 2017
in Izmir - Turkey

EC Certificate of Conformity No: 2017 / 11

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

Serkan Erdur



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 IV of the Directive and the products mentioned
are at Annex III.6

Authorized Representative:

Labex Engineering

Office 206 J&L Center Liubliana Str. 46 1618

Sofia - Bulgaria

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

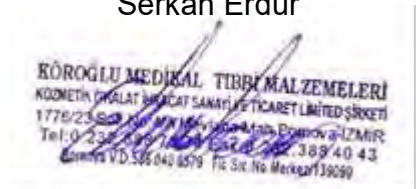
Detailed brand information and first place date, please refer to CE Product List.

Signed this on 15 th September 2017
in İzmir - Turkey

EC Certificate of Conformity No: 2017 / 12

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

Serkan Erdur



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

Menopause Cassette Rapid Test Device

Menopause 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 III.6

Authorized Representative:

Labex Engineering

Office 206 J&L Center Liubliana Str. 46 1618

Sofia - Bulgaria

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 Certificate of Conformity No: 2017 / 13

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

Serkan Erdur



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

Ovulation Cassette Rapid Test Device

Ovulation 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 III.6

Authorized Representative:

Labex Engineering

Office 206 J&L Center Liubliana Str. 46 1618

Sofia - Bulgaria

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

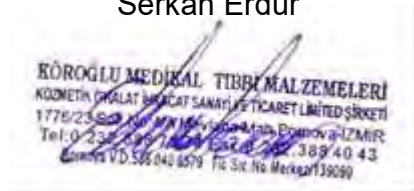
Detailed brand information and first place date, please refer to CE Product List.

Signed this on 15 th September 2017
in İzmir - Turkey

EC Certificate of Conformity No: 2017 / 14

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

Serkan Erdur



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 Izmir - Turkey

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

Trade Names

Laboquick / Certain / Surelab

Products and Models

Pregnancy Cassette Rapid Test Device

Pregnancy 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 III.6

Authorized Representative:

Labex Engineering

Office 206 J&L Center Liubliana Str. 46 1618

Sofia - Bulgaria

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

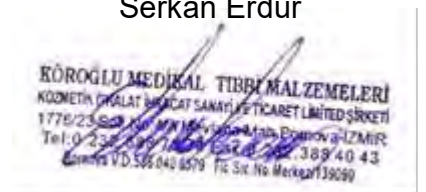
Detailed brand information and first place date, please refer to CE Product List.

Signed this on 15 th September 2017
in Izmir - Turkey

EC Certificate of Conformity No: 2017 / 15

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

Serkan Erdur



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

Strep A Antigen Cassette Rapid Test Device

Strep A Antigen 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 III

Authorized Representative:

Labex Engineering

Office 206 J&L Center Liubliana Str. 46 1618

Sofia - Bulgaria

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

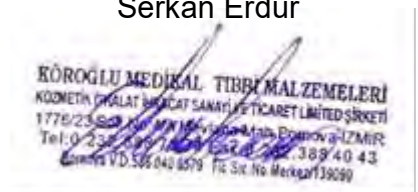
Detailed brand information and first place date, please refer to CE Product List.

Signed this on 15 th September 2017
in İzmir - Turkey

EC Certificate of Conformity No: 2017 / 16

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

Serkan Erdur



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

Gonorrhea Antigen Cassette Rapid Test Device

Gonorrhea Antigen 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 III

Authorized Representative:

Labex Engineering

Office 206 J&L Center Liubliana Str. 46 1618

Sofia - Bulgaria

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
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15223-1: 2012

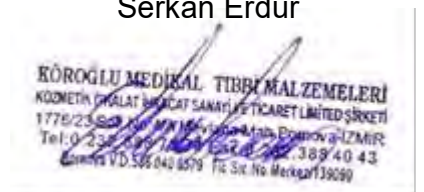
Detailed brand information and first place date, please refer to CE Product List.

Signed this on 15 th September 2017
in İzmir - Turkey

EC Certificate of Conformity No: 2017 / 17

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

Serkan Erdur



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

Chlamydia Antigen Cassette Rapid Test Device

Chlamydia Antigen 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 III

Authorized Representative:

Labex Engineering

Office 206 J&L Center Liubliana Str. 46 1618

Sofia - Bulgaria

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

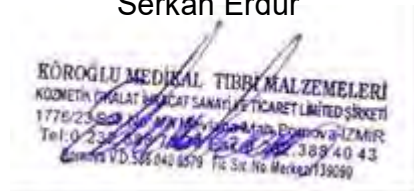
Detailed brand information and first place date, please refer to CE Product List.

Signed this on 15 th September 2017
in İzmir - Turkey

EC Certificate of Conformity No: 2017 / 18

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

Serkan Erdur



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 Izmir - Turkey

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

Trade Names

Laboquick / Certain / Surelab

Products and Models

HBsAb Cassette Rapid Test Device

HBsAb 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

Authorized Representative:

Labex Engineering

Office 206 J&L Center Liubliana Str. 46 1618

Sofia - Bulgaria

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

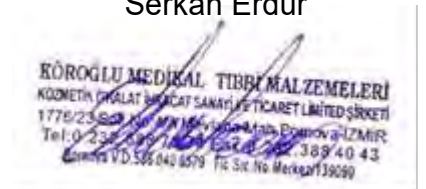
Detailed brand information and first place date, please refer to CE Product List.

Signed this on 15 th September 2017
in Izmir - Turkey

EC Certificate of Conformity No: 2017 / 19

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

Serkan Erdur



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

Anti - HCV Cassette Rapid Test Device

Anti - HCV 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

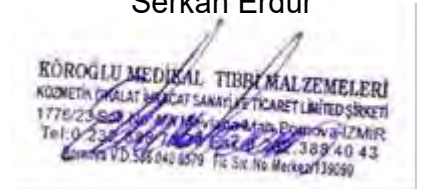
Detailed brand information and first place date, please refer to CE Product List.

Signed this on 15 th December 2013
in İzmir - Turkey

EC Certificate of Conformity No: 2014 / 03

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

Serkan Erdur



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

Anti - HIV 1/2 Cassette Rapid Test Device

Anti - HIV ½ 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 İzmir - Turkey

EC Certificate of Conformity No: 2014 / 01

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

Serkan Erdur

KÖROĞLU MEDİKAL TIBBİ MALZEMELERİ
KOZMETİK İTHALAT İHRACAT SANAYİ VE TİCARET LİMİTED ŞİRKETİ
1776/23 Sok. No: 4/A Mevlana Mah. Bornova İZMİR
Tel: 0 232 389 7404 Fax: 0 232 389 40 43
Bornova V.D.586 040 6579 Tic. Sic.No. Merkez/139090

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 İzmir - Turkey

EC Certificate of Conformity No: 2014 / 02

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

Serkan Erdur

KÖROĞLU MEDİKAL TIBBİ MALZEMELERİ
KOZMETİK İTHALAT İHRACAT SANAYİ VE TİCARET LİMİTED ŞİRKETİ
1776/23 Sok. No: 4/A Mevlana Mah. Bornova-İZMİR
Tel: 0 232 388 7100 Fax: 0 232 388 40 43
Bornova V.D. 586 040 6579 Tic. Sic. No: Merkez/139090