

EC Certificate - Full Quality Assurance

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV, excluding Sections 4 and 6

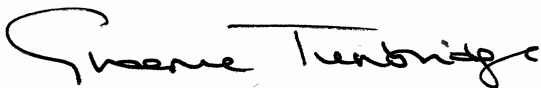
No. CE 724142
Issued To: **Kreatech Biotechnology B.V.**
Vlierweg 20
1032 LG Amsterdam
The Netherlands

In respect of:

Design and manufacture of FISH DNA probes for the evaluation of the risk of Trisomy 21.

on the basis of our examination under the requirements of Council Directive 98/79/EC, Annex IV, the quality system was found to meet the requirements of 98/79/EC Annex IV.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2020-07-10**

Date: **2022-03-21**

Expiry Date: **2025-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. For the placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to 98/79/EC Annex IV Section 4 is required and a letter releasing each batch according to Annex IV Section 6.

This certificate was issued electronically and is bound by the conditions of the contract.

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Supplementary Information to CE 724142

Issued To:

Kreatech Biotechnology B.V.
Vlierweg 20
1032 LG Amsterdam
The Netherlands

Number	Device Name	Intended purpose per IFU
Annex II List B		
IVD0308		
KBI-40002	RCAN1 (21q22)	The RCAN1 (21q22) FISH probe is optimized to detect copy numbers of chromosome 21 at 21q22 on uncultured amniotic cells. This FISH assay will not detect the presence of structural chromosome abnormalities that can also result in birth defects. The probe is recommended to be used in combination with one of the Kreatech Pretreatment kits providing necessary reagents to perform FISH on various sample types for optimal results.
KBI-40003	RB1 (13q14)/RCAN1 (21q22)	The RCAN1 (21q22) specific FISH probe is optimized to detect copy numbers of chromosome 21 at 21q22 on uncultured amniotic cells. The RB1 (13q14) specific FISH probe is optimized to detect copy numbers of chromosome 13 at 13q14 on uncultured amniotic cells. This FISH assay will not detect the presence of structural chromosome abnormalities that can also result in birth defects. The probe is recommended to be used in combination with one of the Kreatech Pretreatment kits providing necessary reagents to perform FISH on various sample types for optimal results.

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

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Number	Device Name	Intended purpose per IFU
KBI-40005	RB1 (13q14)/RCAN1 (21q22), SE X (DXZ1) / SE Y (DYZ3) / SE 18 (D18Z1)	The RCAN1 (21q22) specific FISH probe is optimized to detect copy of numbers of chromosome 21 at 21q22 on uncultured amniotic cells. The RB1 (13q14) specific FISH probe is optimized to detect copy of numbers of chromosome 13 at 13q14 on uncultured amniotic cells. The SE 18 (D18Z1) (Satellite Enumeration) FISH probe is optimized to detect copy of numbers of chromosome 18 at 18p11-18q11 on uncultured amniotic cells. The SE X (DXZ1) FISH probe is optimized to detect copy of numbers of chromosome X at Xp11-Xq11 on uncultured amniotic cells. The SE Y (DYZ3) FISH probe is optimized to detect copy of numbers of chromosome Y at Yp11-Yq11 on uncultured amniotic cells.
KBI-40006	RB1 (13q14)/RCAN1 (21q22), SE X (DXZ1) / SE Y (DYZ3) / SE 18 (D18Z1)	The RCAN1 (21q22) specific FISH probe is optimized to detect copy of numbers of chromosome 21 at 21q22 on uncultured amniotic cells. The RB1 (13q14) specific FISH probe is optimized to detect copy of numbers of chromosome 13 at 13q14 on uncultured amniotic cells. The SE 18 (D18Z1) (Satellite Enumeration) FISH probe is optimized to detect copy of numbers of chromosome 18 at 18p11-18q11 on uncultured amniotic cells. The SE X (DXZ1) FISH probe is optimized to detect copy of numbers of chromosome X at Xp11-Xq11 on uncultured amniotic cells. The SE Y (DYZ3) FISH probe is optimized to detect copy of numbers of chromosome Y at Yp11-Yq11 on uncultured amniotic cells.

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Number	Device Name	Intended purpose per IFU
KBI-40007	RB1 (13q14)/RCAN1 (21q22), SE X (DXZ1) / SE Y (DYZ3) / SE 18 (D18Z1)	The RCAN1 (21q22) specific FISH probe is optimized to detect copy of numbers of chromosome 21 at 21q22 on uncultured amniotic cells. The RB1 (13q14) specific FISH probe is optimized to detect copy of numbers of chromosome 13 at 13q14 on uncultured amniotic cells. The SE 18 (D18Z1) (Satellite Enumeration) FISH probe is optimized to detect copy of numbers of chromosome 18 at 18p11-18q11 on uncultured amniotic cells. The SE X (DXZ1) FISH probe is optimized to detect copy of numbers of chromosome X at Xp11-Xq11 on uncultured amniotic cells. The SE Y (DYZ3) FISH probe is optimized to detect copy of numbers of chromosome Y at Yp11-Yq11 on uncultured amniotic cells.
KBI-40008	RCAN1 (21q22), SE X, SE Y	The RCAN1 (21q22) specific FISH probe is optimized to detect copy numbers of chromosome 21 at 21q22 on uncultured amniotic cells. The SE X (DXZ1) (Satellite Enumeration) FISH probe is optimized to detect copy numbers of chromosome X at Xp11-Xq11 on uncultured amniotic cells. The SE Y (DYZ3) (Satellite Enumeration) FISH probe) is optimized to detect copy numbers of chromosome Y at Yp11-Yq11 on uncultured amniotic cells.

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EC Certificate - Full Quality Assurance Certificate History

Certificate No: **CE 724142**
 Date: **2022-03-21**
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Date	Reference Number	Action
10 July 2020	3145522	First Issue. Transfer from another Notified Body
21 April 2021	3393846	Remove devices part coded KBI-40050, KBI-40051 & KBI-45008 from device table
19 November 2021	3537270	Certificate Renewal
Current	3641512	Change of IVDD expiry date according to Regulation (EU) 2022/112

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