

# **EC DECLARATION OF CONFORMITY**

Doc. Reference No.: DOC-FX9202

**Manufacturer:** Labgenomics Co., Ltd.  
#1204, 12F, 147, Gwanggyo-ro, Yeongtong-gu, Suwon-si,  
Gyeonggi-do 26229, Republic of Korea

**EC Representative:** Obelis S.A.  
Bld. Général Wahis 53  
1030 Brussels, Belgium

**Product Name:** LabGscan™ FRAXA PCR Kit

**Brand Name:** LabGscan™

**Product Identification No.:** FX9202A, FX9202B, FX9202C

**Classification:** Others (neither listed in Annex II, nor self-testing device) according to IVDD(Annex III)

We herewith declare that the above mentioned product meets the provisions of the Council Directive 98/79/EC for In-vitro diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer.

**Standards applied :**

EN ISO 13485:2016, EN ISO 14971:2012,  
EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002/AC:2002,  
EN 13640:2002, EN ISO 23640:2015, EN ISO 15223-1:2016

**Notified Body :**

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**Start of CE-marking:** 2016. 01. 01

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**Signature:**



*President, Seung Hyun Chin*