EC Declaration of Conformity

Manufacturer:	Wuhan HealthCare Biotechnology Co., Ltd. Floor 1-4, Building #8, Optics Valley Precision Medicine Industry Base Phase I, #9 Gaokeyuan 3rd Road, East Lake High-Tech Zone, Wuhan City, Hubei Province, People's Republic of China.
European Representative:	Kingsmead Service B.V. Zonnehof 36, 2632 BE, Nootdorp, Netherland
Trade Name:	Prenatal chromosomes probe detection kit
Name of device:	Fast fluorescence in situ hybridization probe kit
EDMA CODE:	16-02-01-90-00

Classification: **Others of ANNEX II of IVDD**

Conformity Assessment Route: **Annex III**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

General applicable directives:
In Vitro Diagnostic Medical Devices DIRECTIVE 98/79/EC

Harmonized standards:
EN ISO 13485:2016
EN ISO 15223-1:2016
EN ISO 14971:2012
EN ISO 18113-2:2011
EN 13612:2002
EN ISO 17511:2003
EN ISO 23640:2015

Signature:	
Date:	January 13, 2022
Name:	Lambert Nyobe
Title:	International marketing manager
Position:	Wuhan China

Digitally signed by Rusu Ghenadie
Date: 2024.12.17 09:21:49 EET
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