Doc No.: GS20EC30005005

EC Declaration of Conformity

Genesystem Co.,Ltd.

In accordance with Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

WE HEREWITH DECLARE EXCLUSIVELY UNDER SOLE RESPONSIBILITY THAT THE BELOW MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC FOR IN VITRO MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

Product name	Real-time PCR System
Brand name	GENECHECKER®
Model name	UF-300
Cat.No.	1399100200

Applied Directive : 98/79/EC

Classification : General

Document No. : GS-CE-TCF-002

Conformity Assessment Route : Annex III

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Confirmed by:
Genesystem CO.,LTD.

Yujin Seo / CEO

- Applied standards

EN ISO 13485: 2016	Medical devices — Quality management systems — Requirements for regulatory purposes
EN ISO 14971: 2012	Medical devices – Application of risk management to medical devices
EN ISO 15223-1:2016	Symbols for use in the labelling of medical devices
EN 13612: 2002 / AC: 2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 18113-1: 2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labeling) – Part 1: Terms, definitions and general requirements
EN ISO 18113-3: 2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labeling) – Part 3: In vitro diagnostic instruments for professional use
EN 60601-1:2006/A1:2013	Medical electrical equipment – General requirements for basic safety and essential performance (IEC 60601-1:2005/A1:2012)
EN 61010-1:2010	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements (EN 61010-1:2010)
EN 61010-2-101:2017	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment (IEC 61010-2-101:2015)
EN 61326-1:2013	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements (IEC 61326-1:2012)
EN 61326-2-6:2013	ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL AND LABORATORY USE – EMC REQUIREMENTS – PART 2-6: PARTICULAR REQUIREMENTS – IN VITRO DIAGNOSTIC (IVD) MEDICAL EQUIPMENT (IEC 61326-2-6:2012)
EN 55011 : 2016	Industrial, scientific and medical equipment. Radio-frequency disturbance characteristics. Limits and methods of measurement.
EN 60601-1-6:2010/A1:2015	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability (IEC 60601-1-6:2013)
EN 62366:2015	Application of usability engineering to medical devices(IEC 62366:2007)
EN 62304:2006	Medical device software – Software life-cycle processes (IEC 62304:2006)
EN 1041:2008+A1:2013	Information Supplied by the Manufacturer with Medical Devices