Declaration of Conformity

according to Directive 98/79/EC, on in vitro diagnostic medical devices

Maker (Name, Address)	**Getein Biotech, Inc.** No. 9 Bofu Road, Luhe District, Nanjing, 211505, China		
Authorized Representative (Name, Address)	**Lotus Global Co., Ltd** 1 Four Seasons Terrace West Drayton, Middlesex London, UB7 9GG United Kingdom		
Medical device	Description	:	Getein1100 Immunofluorescence Quantitative Analyzer Cardiac Troponin I Fast Test Kit (Immunofluorescence Assay) NT-proBNP Fast Test Kit(Immunofluorescence Assay) hs-CRP+CRP Fast Test Kit (Immunofluorescence Assay) NT-proBNP/cTnI Fast Test Kit (Immunofluorescence Assay) CK-MB/cTnI/Myo Fast Test Kit (Immunofluorescence Assay) D-Dimer Fast Test Kit (Immunofluorescence Assay) PCT Fast Test Kit (Immunofluorescence Assay) β_2-MG Fast Test Kit (Immunofluorescence Assay) mAlb Fast Test Kit (Immunofluorescence Assay) NGAL Fast Test Kit (Immunofluorescence Assay) CysC Fast Test Kit (Immunofluorescence Assay) CK-MB/cTnI Fast Test Kit (Immunofluorescence Assay) HCG+β Fast Test Kit (Immunofluorescence Assay) HbA1c Fast Test Kit (Immunofluorescence Assay) TSH Fast Test Kit (Immunofluorescence Assay) TSH/T3/T4 Fast Test Kit (Immunofluorescence Assay) PCT/CRP Fast Test Kit (Immunofluorescence Assay) CK-MB/cTnI/H-FABP Fast Test Kit (Immunofluorescence Assay) H-FABP Fast Test Kit (Immunofluorescence Assay)	
	Classification of products according to directive	:	Others
	Batch/serial No. Type, production term (if applicable)	:	
Applicable coordination standards:	EN ISO 14971:2012 EN 980:2008 EN 1041:2008 EN ISO 18113-3:2011 IEC 61010-2-101:2015	EN ISO 23640:2015 EN 13612:2002 EN ISO 18113-1:2011 EN-IEC 61326-1:2013 EN-IEC 61326-2-2:2013	EN ISO 13485:2016 EN ISO15223-1:2012 EN ISO 18113-2:2011 EN-IEC 61010-1:2010

Signatory representative declares herein the above mentioned device meets the basic requirements of the European Parliament and the Council's in vitro diagnostic medical devices directive: 98/79/EC Annex III. This declaration of conformity is based on European Parliament and the Council's 98/79/EC directive Annex III. The compiled technical file and quality system document according to 98/79/EC directive Annex III are testified and the quality system certificate has issued by TÜV Rheinland (Shanghai) Co., Ltd.

General Manager: Enben Su

Nanjing, 3rd, Jan, 2017

(place and date of issue)

(name and signature or equivalent marking of authorized person)

2nd Jan 2017 London

Lotus Global Co.,Ltd
Tel:0044-20-75388010,Fax:0044-20-79006187
Four Seasons Terrace,West Drayton,Middlesex
London,UB7 9GG,United Kingdom

Digitally signed by Monastirschii Viorica
Date: 2021.04.20 15:08:32 EEST
Reason: MoldSign Signature
Location: Moldova