



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 <i>2nd/Jan/2017 London</i>		
Medical device	Description :	Geteint 100 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/CTnl Fast Test Kit (Immunofluorescence Assay) CK-MB/CTnl/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/CTnl 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/CTnl/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 ISO 23640:2015	EN ISO 13485:2016
	EN 980:2008	EN 13612:2002	EN ISO15223-1:2012
	EN 1041:2008	EN ISO 18113-1:2011	EN ISO 18113-2:2011
	EN ISO 18113-3:2011	EN-IEC 61326-1:2013	EN-IEC 61010-1:2010
	IEC 61010-2-101:2015	EN-IEC 61326-2-2:2013	
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			
<i>Nanjing, 3rd, Jan, 2017</i> (place and date of issue)		 (name and signature or equivalent marking of authorized person)	