



# Declaration of Conformity



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

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|-----------------------------------------------------|--------------------------------------------------------------------------------------------|--|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Maker</b><br>(Name, Address)                     | <b>Getein Biotech, Inc.</b><br>No. 9 Bofu Road, Luhe District, Nanjing, 211505, China      |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Authorized Representative</b><br>(Name, Address) | <b>Lotus NL B.V.</b><br>Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands. |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Medical device</b>                               | <b>Description :</b>                                                                       |  | FIA8000 Quantitative Immunoassay Analyzer<br>FIA8600 Quantitative Immunoassay Analyzer<br>Cardiac Troponin I Fast Test Kit<br>One Step Test for cTnI (Colloidal Gold)<br>cTnI Rapid Test (Colloidal Gold Assay)<br>One Step Test for NT-proBNP (Colloidal Gold)<br>One Step Test for NT-proBNP/cTnI (Colloidal Gold)<br>One Step Test for CK-MB/cTnI/Myo (Colloidal Gold)<br>One Step Test for hs-CRP+CRP (Colloidal Gold)<br>One Step Test for D-Dimer (Colloidal Gold)<br>One Step Test for PCT (Colloidal Gold)<br>One Step Test for $\beta$ 2-MG (Colloidal Gold)<br>One Step Test for mAlb (Colloidal Gold)<br>One Step Test for NGAL (Colloidal Gold)<br>One Step Test for CysC (Colloidal Gold)<br>One Step Test for HCG+ $\beta$ (Colloidal Gold)<br>One Step Test for HbA1c (Colloidal Gold)<br>One Step Test for PCT/CRP (Colloidal Gold)<br>One Step Test for CK-MB/cTnI/H-FABP (Colloidal Gold)<br>One Step Test for H-FABP (Colloidal Gold)<br>One Step Test for CK-MB/cTnI (Colloidal Gold)<br>One Step Test for CK-MB (Colloidal Gold)<br>One Step Test for TSH (Colloidal Gold)<br>One Step Test for T4/T3 (Colloidal Gold)<br>One Step Test for T3 (Colloidal Gold)<br>One Step Test for T4 (Colloidal Gold)<br>One Step Test for 25-OH-VD (Colloidal Gold)<br>One Step Test for FOB (Colloidal Gold)<br>One Step Test for <i>H. pylori</i> (Colloidal Gold)<br>One Step Test for SAA (Colloidal Gold)<br>Getein1100 Immunofluorescence Quantitative Analyzer<br>Getein1600 Immunofluorescence Quantitative Analyzer<br>Getein1180 Immunofluorescence Quantitative Analyzer<br>Getein1200 Immunofluorescence Quantitative Analyzer<br>Cardiac Troponin I Fast Test Kit (Immunofluorescence Assay)<br>NT-proBNP Fast Test Kit (Immunofluorescence Assay)<br>hs-CRP+CRP Fast Test Kit (Immunofluorescence Assay)<br>NT-proBNP/cTnI Fast Test Kit (Immunofluorescence Assay)<br>CK-MB/cTnI/Myo Fast Test Kit (Immunofluorescence Assay)<br>D-Dimer Fast Test Kit (Immunofluorescence Assay) |



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|  |                                                        | PCT Fast Test Kit (Immunofluorescence Assay)<br>β2-MG Fast Test Kit (Immunofluorescence Assay)<br>mAlb Fast Test Kit (Immunofluorescence Assay)<br>NGAL Fast Test Kit (Immunofluorescence Assay)<br>CysC Fast Test Kit (Immunofluorescence Assay)<br>CK-MB Fast Test Kit (Immunofluorescence Assay)<br>CK-MB/cTnI Fast Test Kit (Immunofluorescence Assay)<br>HCG+β Fast Test Kit (Immunofluorescence Assay)<br>HbA1c Fast Test Kit (Immunofluorescence Assay)<br>PCT/CRP Fast Test Kit (Immunofluorescence Assay)<br>CK-MB/cTnI/H-FABP Fast Test Kit (Immunofluorescence Assay)<br>H-FABP Fast Test Kit (Immunofluorescence Assay)<br>25-OH-VD Fast Test Kit (Immunofluorescence Assay)<br>TSH Fast Test Kit (Immunofluorescence Assay)<br>T3 Fast Test Kit (Immunofluorescence Assay)<br>T4 Fast Test Kit (Immunofluorescence Assay)<br>25-OH-VD Fast Test Kit (Immunofluorescence Assay)<br>FOB Fast Test Kit (Immunofluorescence Assay)<br><i>H. pylori</i> Fast Test Kit (Immunofluorescence Assay)<br>SAA Fast Test Kit (Immunofluorescence Assay)<br>LH Fast Test Kit (Immunofluorescence Assay)<br>FSH Fast Test Kit (Immunofluorescence Assay)<br>AMH Fast Test Kit (Immunofluorescence Assay)<br>PRL Fast Test Kit (Immunofluorescence Assay)<br>CK-MB Control<br>cTnI Control<br>Myo Control<br>NT-proBNP Control<br>D-Dimer Control<br>CRP Control<br>PCT Control<br>β2-MG Control<br>mAlb Control<br>NGAL Control<br>CysC Control<br>H-FABP Control<br>HbA1c Control<br>HCG+β Control<br>CK-MB/cTnI/Myo Control<br>CK-MB/cTnI Control<br>NT-proBNP/cTnI Control<br>TSH Control<br>T4/T3 Control<br>T3 Control<br>T4 Control |        |  |
|  | Classification of products according to directive      | :                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Others |  |
|  | Batch/serial No. Type, production term (if applicable) | :                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |        |  |



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|------------------------------------------|-------------------|----------------------|----------------------|
| Applicable<br>coordination<br>standards: | EN ISO 14971:2012 | EN ISO 23640:2015    | EN ISO 13485:2016    |
|                                          | EN 13612:2002     | EN ISO15223-1:2012   | EN ISO 18113-2:2011  |
|                                          | EN 1041:2008      | EN ISO 18113-1:2011  | EN ISO 18113-3:2011  |
|                                          | IEC 61010-1:2010  | IEC 61010-2-081:2015 | IEC 61010-2-101:2015 |
|                                          | IEC 61326-1:2013  | 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

Nha Trang, 20th, Jul, 2019

(place and date of issue)

(name and signature or equivalent  
marking of authorized person)

