

## DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES



MANUFACTURER:

Beijing Rongrui-Century Science & Technology Co., Ltd.  
3 rd Floor, West zone, No.1Building, No.7Yard, Fengxian  
middle Road, Haidian District, Beijing100094, P.R, China

MEDICAL DEVICE:

Heated Tube

MODEL:

RVTH001, RVTH002

CLASSIFICATION - ANNEX IX:

CLASS II A, RULE 2 ACCORDING TO ANNEX IX OF THE  
MDD

CONFORMITY ASSESSMENT ROUTE:

ANNEX II EXCLUDING SECTION 4

WE, BEIJING RONGRUI-CENTURY SCIENCE & TECHNOLOGY CO., LTD, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES. MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES; INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL. DIRECTIVE 2007/47/EEC ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURE. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DOC.  
STANDARDS APPLIED: *APPLIED EU HARMONIZED STANDARDS.*

NOTIFIED BODY:

TÜV SÜD PRODUCT SERVICE GMBH  
RIDLERSTR 65,  
D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER

0123

(EC) CERTIFICATE(S):

NO. G1 067381 0014 VALID UNTIL: DEC. 1<sup>ST</sup>, 2023

EUROPEAN REPRESENTATIVE: Shanghai International Holding Corp. GmbH (Europe)  
Eiffestrasse 80, 20537 Hamburg, Germany  
DIMDI NO.: DE/0000040627

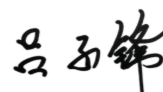
START OF CE-MARKING:

NOT YET

PLACE, DATE OF DECLARATION:

CITY: BEIJING, DATE: NOV. 15<sup>TH</sup> 2021

SIGNATURE:



NAME: LVZFIENG

POSITION: MANAGEMENT REPRESENTATIVE