

DECLARATION OF CONFORMITY

Technical file of the company mentioned below has been inspected and audit has been completed successfully Regulation (EU) 2017/745 on Medical Devices have been taken as reference for these processes

Company Name: Infitek Co., Ltd.

Brand: INFITEK

Related Directives and Annex: Regulation (EU) 2017/745 on Medical Devices

Related Standards: EN 61326-1:2021; EN 61010-1:2010

Product(s): Centrifuges

Type(s)/Model(s): CFG-4ZS; CFG-4ZN; CFG-Mini6R; CFG-Mini7E; CFG-4R; CFG-Mini5D; CFG-Mini7M; CFG-Mini4Y-E; CFG-Mini6Y-E; CFG-Mini4Y; CFG-Mini7Y; CFG-Mini6Y; CFG-Mini10Y-E; CFG-5D; CFG-Mini4B; CFG-4ZB; CFG-Mini10Y; CFG-Mini6B; CFG-Mini10B; CFG-Mini7YS; CFG-4ZBP; CFG-Mini10YS; CFG-5B(BD); CFG-4D-E; CFG-MP2R; CFG-16D; CFG-4BA; CFG-M2Y; CFG-4B(WS); CFG-4ZC; CFG-12D; CFG-4ZCP; CFG-4.5D; CFG-4.5D(PRP); CFG-5B; CFG-4B(PRP); CFG-4B; CFG-16B; CFG-4D(A6-50P); CFG-4ZL; CFG-4D; CFG-16.5B; CFG-Mini15D; CFG-5B(WS); CFG-Mini15R; CFG-6B; CFG-5BL; CFG-12B(HCT); CFG-18.5J; CFG-15Y; CFG-4B(BW); CFG-3B(Cyto); CFG-5DK; CFG-4B(BT); CFG-18.5B; CFG-5B-A; CFG-5B(PRP); CFG-550; CFG-21J; CFG-B5BL; CFG-15D; CFG-14D; CFG-6J; CFG-6D; CFG-B16B; CFG-B16DR; CFG-580; CFG-550J; CFG-20.5B; CFG-B5BL; CFG-25BP; CFG-B16.5B; CFG-B18B; CFG-18.5J; CFG-15D; CFG-5D(Oil); CFG-B550J; CFG-23J; CFG-550J; CFG-B21B; CFG-B5B; CFG-24J; CFG-B20B; CFG-B8B; CFG-17B; CFG-24JL; CFG-5B(Oil); CFG-B580; CFG-20.5B; CFG-4B(Oil); CFG-6DL; CFG-6Y; CFG-21BP; CFG-22BP; CFG-12BP

Parameters: 220V/ 50Hz

Classification: Class I

Examination Period: November 10, 2023

Date of Expiry: November 9, 2028

Review Result: We, Infitek Co., Ltd. declare that during the self-testing and performance evaluation, no Non-compliance according to the requirements of the Regulation (EU) 2017/745 on Medical Devices was detected.

Year of DOC marking: 2023

Signed for and on behalf of

Company: Infitek Co., Ltd.

General Manager: Ben

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