

EU Declaration of Conformity

Manufacturer:

Qingdao Haier Biomedical Technology Co., Ltd.

Address:

No. 280 Fengyuan Road, High-tech Zone,
Qingdao, 266111 Shandong, P.R. China

SRN: CN-MF-000039043

EU Authorized Representative:

Shanghai International Holding Corp. GmbH
(Europe)

Address:

Eiffestrasse 80, 20537 Hamburg, Germany

SRN: DE-AR-000000001

As the manufacturer, we herewith declare under our sole responsibility that the following stated product:

Product Name: Medical Centrifuge

Model: LX-165T2R, LX-60T100-J, LX-155T500R, LX-165T2-J, LX-185T100R,
LX-60T500-J, LX-75L2400R, LX-210L750R, LX-60T100R, LX-185T100-J

Basic UDI-DI:

Model	Basic UDI-DI
LX-165T2R, LX-60T100-J; LX-155T500R, LX-165T2-J; LX-185T100R, LX-60T500-J; LX-60T100R, LX-185T100-J	697444022LX001EG
LX-75L2400R, LX-210L750R	697444022LX002EJ

Of Class: Class A according to Regulation (EU) 2017/746, ANNEX VIII
Classification rules, 2.5. Rule 5

EMDN code: W02069003 CENTRIFUGES

Intended use: This centrifuge can be used as IVD (In vitro diagnostic) laboratory equipment if used together with IVD tubes and IVD diagnostic analysis systems.

The centrifuge separates human blood. Blood is used in numerous diagnostic tests such as hematological screening (e.g. measurement of free hemoglobin), immunological screening (e.g. measurement of thrombocytes levels), cardio-vascular system assessment (e.g. analysis of potassium level).

is in conformity with Regulation (EU) 2017/746 and with any other relevant Union legislation that provides for the issuing of this EU Declaration of Conformity.



Conformity assessment procedure: Annex IX Chapter I, Section 2 of Regulation (EU) 2017/746 (IVDR)
CS Reference NA

Qingdao, 2025-05-28

Ort, Datum / Place, date /
Lieu, date / Luogo, data

Cui Jiehu / PRRC


Name and Funktion / Name and function /
Nom et fonction / Nome e funzione

A red circular stamp with a five-pointed star in the center. The text around the star is in Chinese characters: '山东医疗器械研究所' (Shandong Medical Device Research Institute) at the top and '借款担保无效' (Loan Guarantee Invalid) at the bottom. A number '3702001848918' is visible at the bottom of the stamp.