Advancing Cancer Diagnostics
Improving Lives

Leica
BIOSYSTEMS

EU DECLARATION OF CONFORMITY

We, **Leica Biosystems Nussloch GmbH**, **Heidelberger Str. 17-19**, **69226 Nussloch**, **Germany**

hereby declare under our sole responsibility that the medical device

Product and Trade name	**Leica RM2125 RTS**
Product	Microtome
Risk Class	A
Basic UDI-DI	010404918804579Z
Single Registration Number	DE-MF-000021943
Product description	A precision cutting instrument intended to be used to cut tissue sections, fixed in paraffin wax, into thin slices for subsequent in vitro diagnostic analysis. The device has a vertically-fixed knife which cuts through the paraffin block vertically, and a flywheel mechanism which cuts sections with each turn.

meets the provision European legislation:

- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices (OJ L 117, 5.5.2017, p. 176–332). The procedure according to Annex II and Annex III of the above-mentioned regulation has been followed.

  EN 61010-2-101:2017
  EN ISO 14971:2019

Quality Management System: Certified according to EN ISO 13485:2016 and ISO 9001:2015

Manufacturing site: Leica Microsystems Ltd. Shanghai,
Floor 1, 2, 3A, 4A, and 6, Building T20-1 & Room 301, Building T20-5,
258 Jinzang Road, China (Shanghai) Pilot Free Trade Zone,
Shanghai, PEOPLE'S REPUBLIC OF CHINA

This declaration is effective for products placed on the market as of the date of issue. Any modification of the device not authorized by Leica Biosystems will invalidate this declaration.

Nussloch, 29.06.2022

Andreas Eich
Senior Director CH Nussloch

Robert Gropp
RA/QA Director

Rev. F