Advancing Cancer Diagnostics
Improving Lives

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	**HistoCore Water Bath M**
Product	Thermostatic Water Bath
Risk Class	A
Basic UDI-DI	010404918806079U
Single Registration Number	DE-MF-000021943
Product description	The HistoCore Water Bath M is a waterbath in combination with a slide dryer specifically designed to flatten the floating slides ribbon and afterwards evaporate the water on the cut tissue samples used for histological medical diagnosis by a pathologist, e.g., for cancer diagnosis. The HistoCore Water Bath M is designed for in vitro diagnostic applications.

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
  EN 61326-2-6:2013

- Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88–110)
- Commission Delegated Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances (OJ L 137, 4.6.2015, p. 10–12)

  EN IEC 63000:2018

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

Manufacturing sites: 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, 31.03.2023

DocuSigned by:
Name des Unterzeichners: Andreas Eich
Signiergrund: Ich genehmige dieses Dokument
Signierzeit: 03-Apr-2023 | 06:23:34 PDT
D4A90312D01C40259E0D9534CD96AB6A

Andreas Eich
Senior Director CH Nussloch

DocuSigned by:
Robert Gropp
Name des Unterzeichners: Robert Gropp
Signiergrund: Ich genehmige dieses Dokument
Signierzeit: 31-Mrz-2023 | 11:08:02 MESZ
D12AA0DB0AB5446A970D13E747FB6C99

Robert Gropp
RA/QA Director

Rev. A