Advancing Cancer Diagnostics
Improving Lives

EU DECLARATION OF CONFORMITY

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

declare on our own responsibility, that the medical device

HistoCore BIOCUT

complies with

- the General Safety and Performance Requirements of the 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), Annex I

  EN 61010-2-101:2017
  EN ISO 14971:2012

  Device classification: IVD general/other

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

Nussloch, 13.07.2021

Andreas Hahn
Senior Director CHS

Robert Gropp
RA/QA Manager

Rev. C