Advancing Cancer Diagnostics
Improving Lives

Leica
BIOSYSTEMS

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 MULTICUT

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
  EN 61326-2-6:2013

  Device classification: IVD class A

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,
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Nussloch, 13.07.2021

Andreas Hahn
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Rev. C