Advancing Cancer Diagnostics
Improving Lives

Leica
BIOSYSTEMS

Declaration of Conformity

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

declare on our own responsibility, that the medical device

Leica RM2255

complies with

- the essential requirements of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, Annex III

  EN 61010-2-101:2002
  EN ISO 14971:2012
  EN 61326-2-6:2013

  Device classification: IVD general/other

- 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

  EN 50581:2012

Quality Management System:	Certified according to EN ISO 13485:2012 and ISO 9001:2008
Manufacturing site:	Leica Microsystems Ltd. Shanghai, Building 1, 258 JinZang Road, Jinqiao Export&Processing Zone, Pudong, Shanghai 201206, PRC

Nussloch, 18.09.2017

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