

## 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 RM2265**

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

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- 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

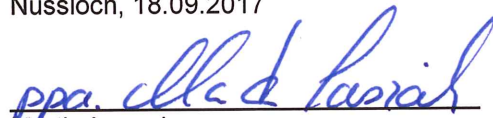
EN 50581:2012

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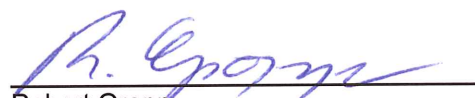
Quality Management System: Certified according to EN ISO 13485:2012 and ISO 9001:2008

Manufacturing site: Leica Microsystems Ltd. Shanghai, Building 1, 258 JinZang Road, Jinqiao Export&Processing Zone, Pudong, Shanghai 201206, PRC

Nussloch, 18.09.2017



Martin Laszak  
Director Customer Service Core Histology &  
Site Leader Nussloch



Robert Gropp  
RA/QA Manager