

## 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

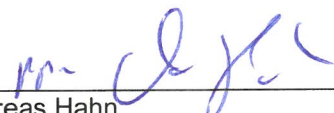
EN ISO 14971:2012


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

  
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Rev. C