

Certificate of Approval

This is to certify that the Management System of:

Roche Diagnostics GmbH QM System Roche Life Science

Nonnenwald 2, 82377 Penzberg, Germany

has been approved by LRQA to the following standards:

ISO 13485:2016



P.G. Cornelissen - Area Manager North Europe

Issued by: Lloyd's Register Deutschland GmbH

for and on behalf of: Lloyd's Register Quality Assurance Limited

Current issue date: 12 December 2018

Expiry date: 20 December 2020

Certificate identity number: 10157926

Original approval(s):

ISO 13485 – 21 December 2011

Approval number(s): ISO 13485 – 0020494

The scope of this approval is applicable to:

Design and manufacturing of life science products (raw materials, components and finished goods) for research and industrial use. Contract manufacturing (raw materials, ingredients, components and finished goods) for IVD and Medical Device Manufactures.



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