



# CERTIFICATE

for a management system as per

EN ISO 13485:2016/AC:2018,  
EN ISO 13485:2016/A11:2021

Evidence of conformity has been furnished.



**Certificate registration No.:**

73 105 6685

**Certificate valid from:**

2024-04-15 **to:** 2026-02-21

# ABX

**ABX advanced biochemical compounds -  
Biomedizinische Forschungsreagenzien GmbH**

Heinrich-Gläser-Str. 10-14

01454 Radeberg / Germany

**Scope - for the European Economic Area:**

Design, development, manufacture and distribution of components for non-sterile, non-active and active medical devices used for the synthesis of radiopharmaceuticals for the EEA



Deutsche  
Akkreditierungsstelle  
D-ZM-14137-01-07



*Dr. Ponick*

Dr. M. Ponick  
Head of Certification body

Release: Darmstadt 2024-04-15  
Certification Body of TÜV Hessen



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This certification confirms the introduction and maintenance of the Management system specified above and is monitored regularly. The current validity is verifiable at [www.proficert.de](http://www.proficert.de). Original certificates contain a glued hologram.

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Translation of German original



# ANNEX



## Associated Sites

**ABX advanced biochemical compounds -  
Biomedizinische Forschungsreagenzien GmbH**  
Heinrich-Gläser-Str. 17  
01454 Radeberg / Germany

**ABX advanced biochemical compounds -  
Biomedizinische Forschungsreagenzien GmbH**  
Heidestraße 70  
01454 Radeberg / Germany

### Scope - for the European Economic Area of application for all the above locations:

Design, development, manufacture and distribution of  
components for non-sterile, non-active and active  
medical devices used for the synthesis of radiopharmaceuticals  
for the EEA

### Certificate registration No.:

73 105 6685

### Certificate valid from:

2024-04-15 to: 2026-02-21

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