

CERTIFICATE

for a management system as per

ISO 13485:2016
EN ISO 13485:2016+AC:2016

Evidence of conformity has been furnished.

ABX

ABX advanced biochemical compounds -
Biomedizinische Forschungsreagenzien GmbH
Heinrich-Gläser-Str. 10-14, 01454 Radeberg / Germany
with additional facilities:
Heidestr. 70, building 208, 01454 Radeberg / Germany
Heinrich-Gläser-Str. 17, 01454 Radeberg / Germany

scope:

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

Certificate registration No. **73 105 6685**

Certificate valid* from 2023-04-04 to **2024-05-26**

Audit report No. 44087413

*previous certificate was valid until 2023-02-21



Deutsche
Akkreditierungsstelle
D-ZM-14137-01-01

D. Jürg

Release: Darmstadt, 2023-04-04
Certification body of TÜV Hessen
– Head of Certification body –

Translation of German original

ABX advanced biochemical compounds -
Biomedizinische Forschungsreagenzien GmbH
Frau Anja Grimm
Heinrich-Gläser-Str. 10-14
01454 Radeberg

**Zertifikate aller Managementsysteme
aus einer Hand**



**Zertifizierungsstelle des
TÜV Hessen**

Ihre Zeichen/Nachricht vom	Unsere Zeichen/Name	Tel.-Durchwahl/Fax-Durchwahl	Datum	Seite
	MS/ Pon/AS	06151 600-331 / -336	12.04.2023	1 von 1

Explanation - "Certificate gap"

Dear Sir or Madam

in individual cases it may happen that certificates are issued with so-called certificate gaps.

The gaps occur when the certification decision, i.e. the release of the procedure by the certification body management, takes place after the expiration date of the previous certificate.

According to ISO 17021-1 para. 9.6.3.2.3, the certificate must correspond to the date of the re-certification decision. Accordingly, DAkkS-accredited certification bodies must ensure that only the date of the certification decision is shown on the certificates.

If you have any further questions, please do not hesitate to contact the certification body of TÜV Hessen.

With kind regards

Dr. Martin Ponick
Head of the certification body

Managementsystem
ISO 9001 / ISO 14001
Zertifiziert durch:



Handelsregister Darmstadt HRB 4915
Id.-Nr.: DE 111665790
Informationen gem. §2 Abs. 1 DL-InfoV
unter www.tuev-hessen.de/impressum
Bankverbindung:
Commerzbank AG
BIC DRESDEFFXXX
IBAN DE23 5008 0000 00971005 00

Aufsichtsratsvorsitzender:
Prof. Dr. Matthias J. Rapp
Geschäftsführer:
Dipl.-Ing. (FH) Henning Stricker
Dipl.-Kfm. Thomas Walkenhorst

Telefon: +49 6151 600-0
Telefax: +49 6151 600-333
www.tuev-hessen.de
TÜV®

Beteiligungsgesellschaft
von



TÜV Technische
Überwachung Hessen GmbH
Management Systeme
Robert-Bosch-Straße 16
64293 Darmstadt
Deutschland