MANUFACTURER'S AUTHORISATION

(This English translation is for reference only. It is not part of the official certificate.)

1. Authorisation number/file number	DE_SN_01_MIA_2022_0020/ 26-5117/91
2. Name of authorisation holder	ABX advanced biochemical compounds Biomedizinische Forschungsreagenzien GmbH (LOC-100018392)
3. Address(es) of manufacturing site(s)	ABX advanced biochemical compounds Biomedizinische Forschungsreagenzien GmbH (LOC-100018392) Heinrich-Gläser-Straße 10-14 01454 Radeberg
4. Legally registered address of authorisation holder	Heinrich-Gläser-Straße 10-14 01454 Radeberg
5. Scope of authorisation and dosage forms	ANNEX 1 and ANNEX 2
6. Legal basis of authorisation	Sect 13 para 1 Arzneimittelgesetz (German Drug Law) Art. 61 para 1 to 3 of Regulation (EU) No. 536/2014 in conjunction with Sect 13 para 5 AMG
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Dr. Brit Kalatz
8. Signature	
9. Date	31/05/2022
10. Annexes attached	Annex 1 and Annex 2 Annex 5 (Name of Qualified Person)

Annex 8 (Manufactured products authorised)

SCOPE OF AUTHORISATION **Annex 1**

Name and address of the site:
ABX advanced biochemical compounds Biomedizinische Forschungsreagenzien GmbH,
Heinrich-Gläser-Straße 10-14, 01454 Radeberg

Human Medicinal Products

AUTHORISED OPERATIONS Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.1	**Sterile Products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms)
	1.1.1 4 Small volume liquids Special requirements 5. Radiopharmaceuticals
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility
	1.6.3 Chemical/Physical
	1.6.4 Biological

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations

This authorisation is only valid for the premises as detailed on the floor plans contained in the version of FB QS 092 (Appendices to the Site Master File [SMF QS 02]) noted by the Authority:
- FB QS 092 (Seite 5): HGS10, Erdgeschoss, Herstellungs- und Kontrollbereich;
- FB QS 092 (Seite 6): HGS10a, Erdgeschoss, Herstellungs- und Kontrollbereich;
- FB QS 092 (Seite 10/11): HS10a, 1. Obergeschoss, Herstellungs- und Kontrollbereich.

to 1.6.3.
This authorisation only applies to the quality control tests contained in the version of the Site Master File (SMF QS 02, 7 Quality Control) noted by the Authority.

to 1.6.4
This authorisation is only valid for testing for bacterial endotoxins (Ph. Eur. 2.6.14).

SCOPE OF AUTHORISATION **Annex 2**

Name and address of the site:
ABX advanced biochemical compounds Biomedizinische Forschungsreagenzien GmbH,
Heinrich-Glaser-Straße 10-14, 01454 Radeberg

Investigational Medicinal Products for Human Use

AUTHORISED OPERATIONS Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.1	**Sterile Products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms)
	1.1.1.4 Small volume liquids Special requirements 5. Radiopharmaceuticals
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility
	1.6.3 Chemical/Physical
	1.6.4 Biological

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations

This authorisation is only valid for the premises as detailed on the floor plans contained in the version of FB QS 092 (Appendices to the Site Master File [SMF QS 02]) noted by the Authority.
- FB QS 092 (Seite 5): HGS10, Erdgeschoss, Herstellungs- und Kontrollbereich;
- FB QS 092 (Seite 6): HGS10a, Erdgeschoss, Herstellungs- und Kontrollbereich;
- FB QS 092 (Seite 10/11): HS10a, 1 Obergeschoss, Herstellungs- und Kontrollbereich.

to 1.6.3:
This authorisation only applies to the quality control tests contained in the version of the Site Master File (SMF QS 02, 7 Quality Control) noted by the Authority.

to 1.6.4:
This authorisation is only valid for testing for bacterial endotoxins (Ph. Eur. 2.6.14).

Annex 5

Name(s) of Qualified Person(s)	Mr. Dr. Marco Müller
	Mr. Dr. René Martin

Annex 8

Products authorised to be manufactured (in accordance with Article 41 and 42 of Directive 2001/83/EC and/or Article 89 and 90 of Regulation (EU) 2019/6, as amended).

Lutetium-177 PSMA-617
18F-PSMA-1007 solution for injection
177LU-DOTA
RADELUMIN (18F-PSMA-1007 bzw. ABX 1007 PSMA)