MANUFACTURER / IMPORTER AUTHORISATION

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

1. Authorisation number/file number	DE_BE_01_MIA_2024_0017/5373/1-Myonex/2
2. Name of authorisation holder	Myonex GmbH (LOC-100072011)
3. Address(es) of manufacturing site(s)	Myonex GmbH Salzufer 13-14 10587 Berlin (LOC-100072011)
4. Legally registered address of authorisation holder	Salzufer 13-14 10587 Berlin
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 Art. 61 para 1 to 3 of Regulation (EU) No. 536/2014 in conjunction with Sect 72 para 2a AMG
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Anja Hildebrandt
8. Signature	On behalf
9. Date	18/07/2024
10. Annexes attached	Annex 1 and Annex 2 Annex 4 (Addresses of Contract Laboratories)

SCOPE OF AUTHORISATION **Annex 1**

Name and address of the site:
Myonex GmbH, Salzufer 13-14, 10587 Berlin

Human Medicinal Products

AUTHORISED OPERATIONS Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.1	**Sterile Products**
	1.1.3 Batch certification
1.5	**Packaging**
	1.5.2 Secondary packing

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

To 1.5.2: Only manuell processes. Secondary packaging operations also cover labeling of primary packed medicinal products. This authorisation is based on site plans no. 1 to no. 4 dated 15. July 2024.

SCOPE OF AUTHORISATION **Annex 2**

Name and address of the site:
Myonex GmbH, Salzufer 13-14, 10587 Berlin

Investigational Medicinal Products for Human Use

AUTHORISED OPERATIONS
Manufacturing Operations (according to part 1)
Importation of Investigational Medicinal Products (according to part 2)

Part 1 - MANUFACTURING OPERATIONS	
1.1	**Sterile Products**
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms)
	1.2.1.1 Capsules, hard shell
	1.2.1.2 Capsules, soft shell
	1.2.1.5 Liquids for external use
	1.2.1.6 Liquids for internal use
	1.2.1.11 Semi-solids
	1.2.1.17 Other overencapsulation of solid dosage forms for oral use
	1.2.2 Batch certification
1.3	**Biological medicinal products**
	1.3.2 Batch certification
	1.3.2.1 Blood products
	1.3.2.2 Immunological products
	1.3.2.3 Cell therapy products
	1.3.2.4 Gene therapy products
	1.3.2.5 Biotechnology products
	1.3.2.6 Human or animal extracted products

	1.3.2.7 Tissue engineered products
1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of:
	1.4.1.1 Herbal products
	1.4.3 Other External storage of documents, reserve samples and reference samples for Hubertus Pharmacy Berlin regarding completed studies that were covered by Hubertus Pharmacy's Berlin manufacturing authorization.
1.5	**Packaging**
	1.5.1 Primary Packing
	1.5.1.1 Capsules, hard shell
	1.5.1.2 Capsules, soft shell
	1.5.1.3 Chewing gums
	1.5.1.5 Liquids for external use
	1.5.1.6 Liquids for internal use
	1.5.1.8 Other solid dosage forms
	1.5.1.11 Semi-solids
	1.5.1.13 Tablets
	1.5.2 Secondary packing

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

To 1.2, 1.4 and 1.5:
Only manual processes.

To 1.2.1.5, 1.2.1.6, 1.2.1.11
Also production of auxiliary medicinal products.

To 1.3.2:
The certification of investigational medicinal products that belong to one of the groups of medicinal products listed in Section 15 para. 3 no. 1 and no. 4 or Section 15 para. 3a no. 3, 4 and 5 AMG is excluded.

To 1.4.1.1:
Only processing of finished herbal active ingredients to liquids and capsules (hard shell), including packaging and batch release.

To 1.5.2:
Secondary packaging operations also cover labeling of primary packed investigational medicinal products and auxiliary medicinal products as well as the packaging of secondary packaging into additional packaging and its labeling.

Permitted manufacturing operations also cover medicinal products for compassionate use programs according to Sect 21 para 2 no. 3 German Drug Law in conjunction with Sect 1 Arzneimittel-Härtefall-Verordnung (German Ordinance on Medicinal Products for Compassionate Use).

This authorisation is based on site plans no. 1 to no. 4 dated 15. July 2024.

Part 2 - IMPORTATION OF INVESTIGATIONAL MEDICINAL PRODUCTS	
2.2	**Batch certification of imported investigational medicinal products**
	2.2.1 Sterile products
	2.2.1.1 Aseptically prepared
	2.2.1.2 Terminally sterilised
	2.2.2 Non-sterile products
	2.2.3 Biological products
	2.2.3.1 Blood products
	2.2.3.2 Immunological products
	2.2.3.3 Cell therapy products
	2.2.3.4 Gene therapy products
	2.2.3.5 Biotechnology products
	2.2.3.6 Human or animal extracted products
	2.2.3.7 Tissue engineered products
2.3	**Other importation activities**
	2.3.1 Site of physical importation
	2.3.2 Importation of intermediate which undergoes further processing

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

To 2.2:
Also batch certification of imported comparators and auxiliary medicinal products.

Also batch certification of medicinal products for compassionate use programs according to Sect 21 para 2 no. 3 German Drug Law in conjunction with Sect 1 Arzneimittel-Härtefall-Verordnung (German Ordinance on Medicinal Products for Compassionate Use).

To 2.2.3
The certification of investigational medicinal products that belong to one of the groups of medicinal products listed in Section 15 para. 3 no. 1 and no. 4 or Section 15 para. 3a no. 3, 4 and 5 AMG is excluded.

To 2.3.2:
Importation of granulate material or premixed formulations as intermediate products for manufacture of solutions or suspensions or to be used as capsule fillings.

Importation of bulk dosage forms for packaging of patient-specific dosing units by singling out and dosage assembling (tablets and capsules).

This authorisation is based on site plans no. 1 to no. 4 dated 15. july 2024.

Address(es) of Contract Laboratories	TECHPharm GmbH Draisstraße 14 76646 Bruchsal - Microbiological: other tests than sterility - Chemical/Physical - Biological SGS INSTITUT FRESENIUS GmbH Im Maisel 14 65232 Taunusstein - Microbiological: sterility - Microbiological: other tests than sterility SGS Institut Fresenius GmbH Tegeler Weg 33 10589 Berlin - Chemical/Physical