MANUFACTURER'S AUTHORISATION

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

1. Authorisation number/file number	DE_NW_05_MIA_2021_0002/24.05.03-075
2. Name of authorisation holder	WESSLING GmbH
3. Address(es) of manufacturing site(s)	WESSLING GmbH Johann-Krane-Weg 42 48149 Münster WESSLING GmbH Oststraße 7 (gem. Plan vom 03.09.2013) floor Ebene Dachboden, room GMP-Archiv 48341 Altenberge
4. Legally registered address of authorisation holder	Oststraße 7 48341 Altenberge
5. Scope of authorisation and dosage forms	ANNEX 1
6. Legal basis of authorisation	Sect 13 para 1 and sect 72 para 1 Arzneimittelgesetz (German Drug Law)
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Dr. Petra Rempe
8. Signature	On behalf
9. Date	16/02/2021

10. Annexes attached

Annex 1
Annex 5 (Name of Qualified Person)

SCOPE OF AUTHORISATION **Annex 1**

Name and address of the site:
WESSLING GmbH, Johann-Krane-Weg 42, 48149 Münster

Human Medicinal Products

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

Part 1 - MANUFACTURING OPERATIONS	
1.1	**Sterile Products**
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility
	1.6.2 Microbiological: non-sterility
	1.6.3 Chemical/Physical

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

Regarding point 1.2.2:
Non-sterile products in liquid, semi-solid and solid dosage forms

External warehouse for archiving GMP-relevant documents:
Lager 3000 GmbH
Wiesenstr. 5-9
26215 Wiefelstede

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.1 Microbiological: sterility
	2.1.2 Microbiological: non-sterility
	2.1.3 Chemical/Physical
2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile products
	2.2.1.1 Aseptically prepared
	2.2.1.2 Terminally sterilised

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

Site of physical importation:
Med-X-Press GmbH
Pracherstieg 1
38644 Goslar

External warehouse for archiving GMP-relevant documents:
Lager 3000 GmbH
Wiesenstr. 5-9
26215 Wiefelstede

SCOPE OF AUTHORISATION **Annex 1**

Name and address of the site:
WESSLING GmbH, Oststraße 7, (gem. Plan vom 03.09.2013), floor Ebene Dachboden, room GMP-Archiv , 48341 Altenberge

Human Medicinal Products

AUTHORISED OPERATIONS Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.1	**Sterile Products**
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility
	1.6.2 Microbiological: non-sterility
	1.6.3 Chemical/Physical

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

No analytical operations, only archiving of documents of the activities regarding points 1.1.3, 1.2.2, 1.6.1, 1.6.2 and 1.6.3

Annex 5

Name(s) of Qualified Person(s)	Mr. Dr. Maik Siebelmann
	Mr. Dr. Ludger Josef Wedy
	Mrs. Carolin Redecker
	Mrs. Dr. Nicole Kordek