

裕利股份有限公司 函

聯絡地址：台北市南京東路四段126號10樓之1至之3

聯絡人員：劉小姐

聯絡電話：02-25700064 分機：23323

聯絡傳真：02-25798587

電子信箱：haorder@zuelligpharma.com

受文者：天主教中華聖母修女會醫療財團法人*

發文日期：中華民國112年02月15日

發文字號：112 裕字-第000256號

主旨：本公司銷售台灣優時比貿易有限公司之產品「Vimpat 10mg/ml solution for infusion(維帕特10毫克/毫升輸液溶液)」(衛部藥輸字第026283號)，二月底前恢復正常供貨通知，暨專案進口之「Vimpat 10mg/ml solution for infusion」(健保代碼: X000245238) 調整出貨事宜，如說明段。

說明：

- 一、本公司銷售台灣優時比貿易有限公司之產品「Vimpat 10mg/ml solution for infusion(維帕特 10毫克/毫升輸液溶液)」承蒙 貴院採用，特此致謝。
- 二、接獲原廠通知「Vimpat 10mg/ml solution for infusion(維帕特10毫克/毫升輸液溶液)」(衛部藥輸字第026283號)，將在112年2月底前恢復正常供應。
- 三、目前供應之專案進口「Vimpat 10mg/ml solution for infusion」(簽審文件編號 DHS00001226631；健保代碼: X000245238) 在二月底前將調整出貨。
- 四、原包裝與專案進口藥品「維帕特10毫克/毫升輸液溶液 (Vimpat 10mg/ml solution for infusion)」之比較如下：

	原包裝	專案進口
製造廠	UCB PHARMA S.A. CHEMIN DU FORIEST, B-1420 BRAINE-L'ALLEUD, BELGIUM	UCB PHARMA S.A. Patheon Italia S.p.A.
批號	6125004(預計 2023.02 底出貨) 6125005(預計 2023.02 底出貨)	6106209
健保碼	BC26283238	X000245238
健保價格	1,083 元/Vial	1,083 元/Vial
健保生效	111.01.01~迄今	112.01.01~112.12.31
盒裝	每盒 5 vials	每盒 1 vial

五、關於原包裝與專案進口包裝圖檔比較表，如附件1。

六、特此通知，造成不便之處，懇請見諒，並請繼續支持本公司為禱。

附件：原廠公文及相關文件。





Inspired by patients.
Driven by science.

台灣優時比貿易有限公司 函

地址：10551 台北市松山區敦化北路 88 號 12 樓之 2

電話：(02) 8979-6177 轉 14

傳真：(02) 8771-7924

聯絡人：謝儒逸

電子信箱：louie.hsieh@ucb.com

受文者：裕利股份有限公司

發文日期：中華民國 112 年 02 月 13 日

發文字號：優時比第 112007 號

速別：速件

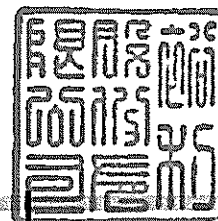
密等及解密條件或保密期限：普通

附件：1. Vimpat 10mg/ml solution for infusion 原包裝與專案進口包裝圖檔比較表
2. 藥品檢驗規格成績書 COA

主 旨：本公司授權 貴公司經銷之藥品：「維帕特 10 毫克/毫升輸液溶液 (Vimpat 10mg/ml solution for infusion)」(衛部藥輸字第 026283 號)，二月底前恢復正常供貨通知，暨本公司專案進口之「Vimpat 10mg/ml solution for infusion」(健保代碼：X000245238) 調整出貨事宜，敬請轉知相關醫療院所。

說 明：

- 一、「維帕特 10 毫克/毫升輸液溶液 (Vimpat 10mg/ml solution for infusion)」(衛部藥輸字第 02628 號；健保代碼：BC26283238)，將在 112 年 2 月底前恢復正常供應。
- 二、目前供應之專案進口「Vimpat 10mg/ml solution for infusion」(簽審文件編號 DHS00001226631；健保代碼：X000245238) 在二月底前將調整出貨，造成不便之處，敬請見諒。
- 三、原包裝與專案進口藥品「維帕特 10 毫克/毫升輸液溶液 (Vimpat 10mg/ml solution for infusion)」之比較如下：





Inspired by patients.
Driven by science.

	原包裝	專案進口
製造廠	UCB PHARMA S.A CHEMIN DU FORIEST, B-1420 BRAINE-L'ALLEUD, BELGIUM	UCB PHARMA S.A Patheon Italia S.p.A
批號	6125004(預計 2023.02 底出貨) 6125005(預計 2023.02 底出貨)	6106209
健保碼	BC26283238	X000245238
健保價格	1,083 元/Vial	1,083 元/Vial
健保生效	111.01.01~迄今	112.01.01~112.12.31
盒裝	每盒 5 vials	每盒 1 vial

四、關於原包裝與專案進口包裝圖檔比較表，如附件 1。

端此

順頌 商祺

正本：裕利股份有限公司

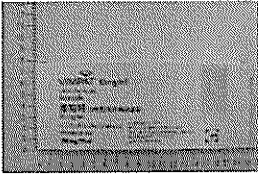
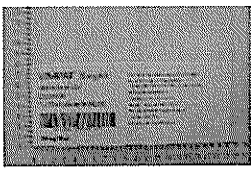
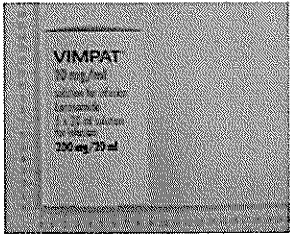
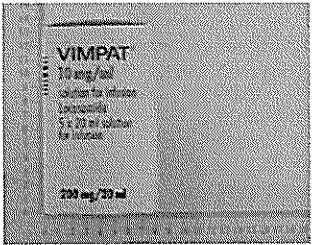
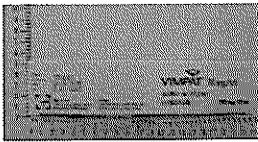
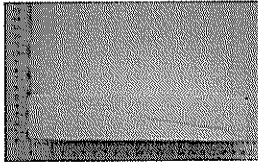
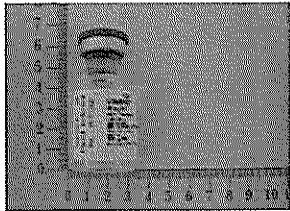
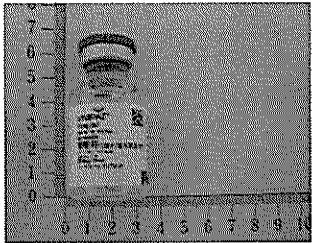
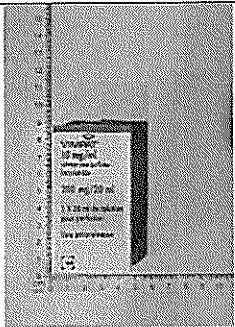
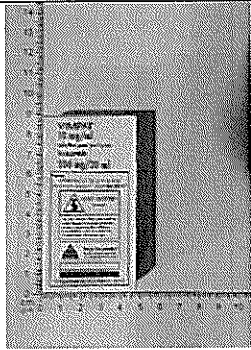
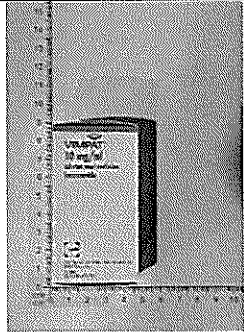
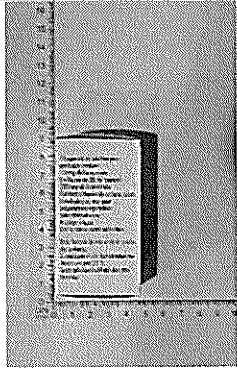
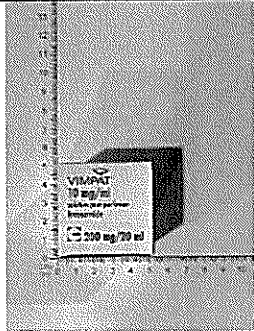
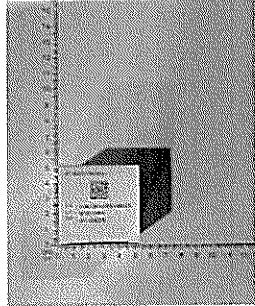
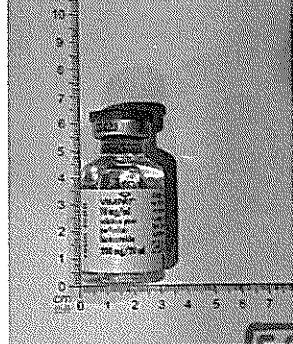
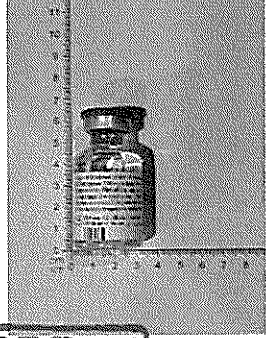


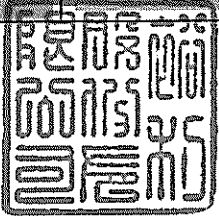
台灣優時比貿易有限公司

負責人 Alexandre Martra

中 華 民 國 一 百 一 十 二 年 二 月 十 三 日

附件: Vimpat 10mg/ml solution for infusion 包裝對照

維帕特 10 毫克/毫升輸液溶液 (Vimpat 10mg/ml solution for infusion) 外盒包裝白底尺規照				
原包裝盒裝 (每盒 5 vials)				
				
專案進口盒裝 (每盒 1 vial)				
				



BATCH RELEASE CERTIFICATE

Name of product, dosage form, package size:	VIMPAT 10MG/ML, solution for infusion (20 ml), 5 injection vials
Strength / Potency:	One ml solution for infusion contains 10 mg Lacosamide.
Article Number:	1008788
Importing Country:	TAIWAN, PROVINCE OF CHINA
Batch Number:	6125004
Date of manufacture:	Jul 25, 2022
Expiry Date:	Jul 24, 2025
Place of manufacture of bulk product:	UCB Pharma SA, 1420 Braine-L' Alleud, Belgium
Place of manufacture of finished product:	Aesica Pharmaceuticals GmbH 40789 Monheim, Germany
Place of final release:	Aesica Pharmaceuticals GmbH 40789 Monheim, Germany
Marketing Authorization Number:	026283
Storage Conditions:	Do not store above 25°C
Remarks:	

Results are taken from the bulk manufacturer's
certificate of analysis.

Results of Analysis: attached Certificate of Analysis

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Relevant Deviations/OOS: no

The above mentioned batch is released by the responsible qualified person.

Aesica Pharmaceuticals GmbH
40789 Monheim

Signed by

Janika Brunk



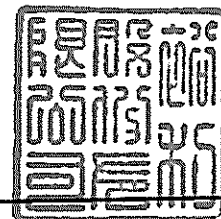
Function

Qualified Person

Date

Feb 07, 2023 13:05

This document has been electronically approved and signed.



Report: BRC V 5.5
ID: J11505452

LABS 4.2

Page 1 of 1
ZA101004/1PA258281

Aesica Pharmaceuticals GmbH
Alfred-Nobel-Straße 10
40789 Monheim
Germany

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F: +49 2173 335 1020
www.recipharm.com

Sitz: Monheim am Rhein. Registergericht und
Registernummer: Amtsgericht Düsseldorf, HRB 64322
Geschäftsführung: Luc Burgard, Dr. Werner Schick
Steuernummer: 135/5713/2423, UST-Id. Nr: DE275410385

Certificate of Analysis

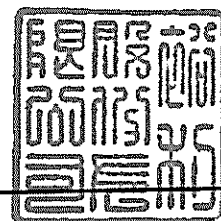
Product name: VIMPAT 10MG/ML,
 solution for infusion (20 ml), 5 injection vials
Article no: 1008788
Specification: spec-100843-1 / 6 from Sep 30, 2022
Batch no: 6125004

Quality characteristic	Requirement	Actual
Properties, description, visual examination		
primary packaging material	20 ml colorless glass with a grey rubber stopper and a flanged aluminum cap with tear-off seal	complies
content	Clear and colorless liquid	complies
Properties, volume		
extractable volume	NLT 20.0 mL	21.0 mL
Identity, HPLC examination		
Lacosamide	Retention time corresponds to retention time of standard	complies
Identity, UV-VIS examination		
Lacosamide	Conforms to UV-spectrum of standard	complies
Identity		
Identification tests-General		
Sodium	Dense white precipitate	complies
Chloride	Curdled white precipitate, soluble in ammonia	complies
Purity, potentiometric examination		
pH value	3.8 - 4.5	3.9
Purity, particulate matter, electronic particle test (HIAC)		
particles/unit $\geq 10 \mu\text{m}$	NMT 6000 particles / vial	228 per unit
particles/unit $\geq 25 \mu\text{m}$	NMT 600 particles / vial	12 per unit
Particulate contamination		
Visible particles	Practically free from visible particles	complies

Certificate of Analysis

Product name: VIMPAT 10MG/ML,
 solution for infusion (20 ml), 5 Injection vials
Article no: 1008788
Specification: spec-100843-1 / 6 from Sep 30, 2022
Batch no: 6125004

Quality characteristic	Requirement	Actual
Assay, HPLC examination		
Lacosamide	95.0 - 105.0 %	99.9 %
Purity, HPLC examination		
Desacetyl-lacosamide (SPM 6912) Impurity D	NMT 0.20 %	< 0.10 %
Any other single impurity (except synthesis impurities)	NMT 0.20 %	< 0.10 %
Total degradation products	NMT 1.0 %	not determinable
Microbiological purity		
sterility	sterile	complies
Microbiological purity		
bacterial endotoxins	NMT 8.3 EU/ml	< 1.0 EU per mL



Certificate of Analysis

Product name: VIMPAT 10MG/ML,
solution for infusion (20 ml), 5 Injection vials
Article no: 1008788
Specification: spec-100843-1 / 6 from Sep 30, 2022
Batch no: 6125004

VIMPAT 10MG/ML,
solution for infusion (20 ml), 5 Injection vials of the above described batch meet the specification.

Aesica Pharmaceuticals GmbH
40789 Monheim

Signed by

Janika Brunk



Function

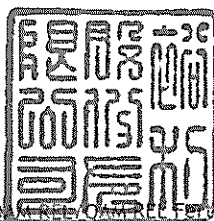
Qualified Person

Date

Feb 07, 2023 13:05

This document has been electronically approved and signed.

SAP Material No	1008788	
SAP Material Name	VIMPAT IV 10MG/ML TWN 005V (20ML)	
Date of Control / Datum der Kontrolle	06.02.2023	
Order No. / Auftrags-Nr.	20231865 ✓	
Folding-Box / Faltschachtel		
Material-No. / Material-Nr.	CIB72282D 4023518	✓
Batch No. / Chargen-Nr.	6125004	✓
MFR / Herstellungsdatum	25/04/2022	✓
Expiry date / Verfalldatum	24/04/2025	✓
Bollini / Vignette	✓	✓
Other variable Imprints / Sonstige variable Aufdrucke	✓	✓
Serial numbers exist and checked / Serialisierungsnummern vorhanden und geprüft	✓	✓
Tamper-evident closure / Originalitätsverschluss intakt	[X] ja [] n/a	✓
Information for use / Gebrauchsinformation		
Material-No. / Material-Nr.	CIB72283F 4025025	✓
Blisterstreifen / Beutel / Etikett		
Material-No. / Material-Nr.	CIB72284B 4021803	✓
Batch No. / Chargen-Nr.	6125004	✓
MFR / Herstellungsdatum	25/04/2022	✓
Expiry date / Verfalldatum	24/04/2025	✓
Dosier- / Applikationshilfen		
Existent / vorhanden (z. B. Oral Dosing System, Measuring Cup / Dosierspritze, Messbecher)	✓	✓
Visual impression - printed image variable data, technical condition of all components / visueller Eindruck - Druckbild variable Daten, technischer Zustand aller Komponenten	OK	
In compliance with the present packaging instruction / Übereinstimmung mit Vorgaben im Verpackungsschein-Nr.		08
Enclosed packaging materials are compliant with the present packaging instruction / Beigelegte Packmittel entsprechen Vorgaben im Verpackungsschein		✓
No. of Retain Samples / Anz. Rückstellmuster: PRM: 2 Pack.	2	✓
Checked Amount / Kontrollierte Menge	2	
Remarks / Bemerkungen (siehe ggf. Rückseite)	✓	
Administrator / Sachbearbeiter (check of packages / Prüfung der Packungen)	Datum 06. FEB. 2023	Kürzel O.H. Stora
Administrator / Sachbearbeiter (check against packaging instruction including check of completeness of finished product / Abgleich der Daten mit VP-Schein inkl. Prüfung auf Vollständigkeit der Fertigware)	Datum 06. FEB. 2023	Kürzel Lm
Qualified Person	Datum 07. FEB. 2023	Unterschrift d. B. R.



BATCH RELEASE CERTIFICATE

Name of product, dosage form, package size:	VIMPAT 10MG/ML, solution for infusion (20 ml), 5 injection vials
Strength / Potency:	One ml solution for infusion contains 10 mg Lacosamide.
Article Number:	1008788
Importing Country:	TAIWAN, PROVINCE OF CHINA
Batch Number:	6125005
Date of manufacture:	Jul 25, 2022
Expiry Date:	Jul 24, 2025
Place of manufacture of bulk product:	UCB Pharma SA, 1420 Braine-L' Alleud, Belgium
Place of manufacture of finished product:	Aesica Pharmaceuticals GmbH 40789 Monheim, Germany
Place of final release:	Aesica Pharmaceuticals GmbH 40789 Monheim, Germany
Marketing Authorization Number:	026283
Storage Conditions:	Do not store above 25°C
Remarks:	

Results are taken from the bulk manufacturer's certificate of analysis.

Results of Analysis: attached Certificate of Analysis

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

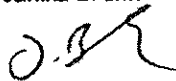
Relevant Deviations/OOS: no

The above mentioned batch is released by the responsible qualified person.

Aesica Pharmaceuticals GmbH
40789 Monheim

Signed by

Janika Brunk



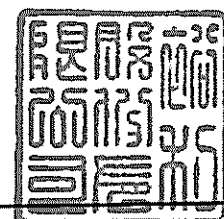
Function

Qualified Person

Date

Feb 07, 2023 15:46

This document has been electronically approved and signed.



Report: BRC V 5.5
ID: J11505528

LABS 4.2

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ZA101017/1PA258354

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Germany

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www.recipharm.com

Sitz: Monheim am Rhein, Registergericht und
Registernummer: Amtsgericht Düsseldorf, HRB 64322
Geschäftsführung: Luc Burgard, Dr. Werner Schick
Steuernummer: 135/5713/2423, UST-Id. Nr: DE275410385

Certificate of Analysis

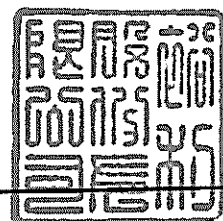
Product name: VIMPAT 10MG/ML,
 solution for infusion (20 ml), 5 injection vials
Article no: 1008788
Specification: spec-100843-1 / 6 from Sep 30, 2022
Batch no: 6125005

Quality characteristic	Requirement	Actual
Properties, description, visual examination		
primary packaging material	20 ml colorless glass with a grey rubber stopper and a flanged aluminum cap with tear-off seal	complies
content	Clear and colorless liquid	complies
Properties, volume		
extractable volume	NLT 20.0 mL	21.0 mL
Identity, HPLC examination		
Lacosamide	Retention time corresponds to retention time of standard	complies
Identity, UV-VIS examination		
Lacosamide	Conforms to UV-spectrum of standard	complies
Identity Identification tests-General		
Sodium	Dense white precipitate	complies
Chloride	Curdled white precipitate, soluble in ammonia	complies
Purity, potentiometric examination		
pH value	3.8 - 4.5	3.9
Purity, particulate matter, electronic particle test (HIAC)		
particles/unit $\geq 10 \mu\text{m}$	NMT 6000 particles / vial	228 per unit
particles/unit $\geq 25 \mu\text{m}$	NMT 600 particles / vial	12 per unit
Particulate contamination		
Visible particles	Practically free from visible particles	complies

Certificate of Analysis

Product name: VIMPAT 10MG/ML,
 solution for infusion (20 ml), 5 Injection vials
Article no: 1008788
Specification: spec-100843-1 / 6 from Sep 30, 2022
Batch no: 6125005

Quality characteristic	Requirement	Actual
Assay, HPLC examination		
Lacosamide	95.0 - 105.0 %	99.9 %
Purity, HPLC examination		
Desacetyl-lacosamide (SPM 6912) Impurity D	NMT 0.20 %	< 0.10 %
Any other single impurity (except synthesis impurities)	NMT 0.20 %	< 0.10 %
Total degradation products	NMT 1.0 %	not determinable
Microbiological purity		
sterility	sterile	complies
Microbiological purity		
bacterial endotoxins	NMT 8.3 EU/ml	< 1.0 EU per mL



Certificate of Analysis

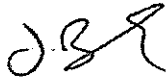
Product name: VIMPAT 10MG/ML,
solution for infusion (20 ml), 5 injection vials
Article no: 1008788
Specification: spec-100843-1 / 6 from Sep 30, 2022
Batch no: 6125005

VIMPAT 10MG/ML,
solution for infusion (20 ml), 5 injection vials of the above described batch meet the specification.

Aesica Pharmaceuticals GmbH
40789 Monheim

Signed by

Janika Brunk



Function

Qualified Person

Date

Feb 07, 2023 15:46

This document has been electronically approved and signed.

SAP Material No	1008788	
SAP Material Name	VIMPAT IV 10MG/ML TWN 005V (20ML)	
Date of Control / Datum der Kontrolle	07.02.2023	
Order No. / Auftrags-Nr.	20231520 ✓	
Folding-Box / Faltschachtel		
Material-No. / Material-Nr.	CIB 722820 4023818	✓
Batch No. / Chargen-Nr.	6125005	✓
MFR / Herstellungsdatum	25/07/2022	✓
Expiry date / Verfalldatum	24/07/2025	✓
Bollini / Vignette	/	✓
Other variable Imprints / Sonstige variable Aufdrucke	/	✓
Serial numbers exist and checked / Serialisierungsnummern vorhanden und geprüft	/	✓
Tamper-evident closure / Originalitätsverschluss intakt	[X] ja [] n/a	✓
Information for use / Gebrauchsinformation		
Material-No. / Material-Nr.	CIB 72283F 4025025	✓
Blisterstreifen / Beutel / Etikett		
Material-No. / Material-Nr.	CIB 72284B 4021803	✓
Batch No. / Chargen-Nr.	6125005	✓
MFR / Herstellungsdatum	25/07/2022	✓
Expiry date / Verfalldatum	24/07/2025	✓
Dosier- / Applikationshilfen		
Existent / vorhanden (z. B. Oral Dosing System, Measuring Cup / Dosierspritze, Messbecher)	/	✓
Visual impression - printed image variable data, technical condition of all components / visueller Eindruck - Druckbild variable Daten, technischer Zustand aller Komponenten	ok	
In compliance with the present packaging instruction / Übereinstimmung mit Vorgaben im Verpackungsschein-Nr.		08
Enclosed packaging materials are compliant with the present packaging instruction / Beigelegte Packmittel entsprechen Vorgaben im Verpackungsschein		✓
No. of Retain Samples / Anz. Rückstellmuster: PRM: 2 Pack.	2	✓
Checked Amount / Kontrollierte Menge	2	
Remarks / Bemerkungen (siehe ggf. Rückseite)	/	
Administrator / Sachbearbeiter (check of packages / Prüfung der Packungen)	Datum 07. FEB. 2023	Kürzel Brod
Administrator / Sachbearbeiter (check against packaging instruction including check of completeness of finished product / Abgleich der Daten mit VP-Schein inkl. Prüfung auf Vollständigkeit der Fertigware)	Datum 07. FEB. 2023	Kürzel Oster
Qualified Person	Datum 07. FEB. 2023	Unterschrift

