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Contact Person	
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Distribution Territory	CZ, SK
Medical Devices distributed	Techno life s.r.o.

3 EN ISO 13485 Qualification assessment EN ISO 13485 Bewertung der Qualifizierung			
No.	requirement Anforderung	evaluation Bewertung	evidence Nachweise
1.	Documented QMS available <i>Dokumentiertes QMS vorhanden</i>	☒ compliance confirmed ☐ recommendation ☐ deviation ☐ n/a, justification:	A QMS in accordance with ISO 9001:2015 is in place. It was not technically possible to inspect the documentation during the audit (as it is paper-based). However, the audit participants were able to provide a coherent explanation of the processes.
2.	ISO 13485 / ISO 9001 certification available <i>Zertifizierung nach ISO 13485 / ISO 9001 vorhanden</i>	☒ compliance confirmed ☐ recommendation ☐ deviation ☐ n/a, justification:	Certificate acc. to ISO 9001:2015 (26.08.2024, valid until 24.08.2027), scope: Distribution of medicinal products, medical devices, medicines, excipients and complementary product ranges. Manufacture of own products. The company is regularly (unannounced) inspected by the Czech health authority (Czech State Institute for Drug Control, SUKL). The authority checks that the distributor complies with all regulations regarding storage and transport. The distributor is

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			registered with the authority in respect of the products it distributes.
3.	Experience in medical device distribution <i>Erfahrung im Vertrieb von Medizinprodukten</i>	☒ compliance confirmed ☐ recommendation ☐ deviation ☐ n/a, justification:	2020: company formation 2021: initial certification 2024: distribution of medical devices and medicinal products, manufacture and distribution of own products (food supplements)
4.	Regulatory knowledge demonstrated <i>Nachgewiesene Fachkompetenz in regulatorischen Fragen</i>	☒ compliance confirmed ☐ recommendation ☐ deviation ☐ n/a, justification:	See ISO 9001 certification with appropriate scope.
5.	Storage and transportation procedures available <i>Lager- und Transportverfahren vorhanden</i>	☒ compliance confirmed ☐ recommendation ☐ deviation ☐ n/a, justification:	The temperature is monitored during storage and transport and maintained at 20–21 degrees. In the warehouse, the temperature sensor is read and checked weekly. The external transport provider also delivers under temperature-controlled conditions (in accordance with Czech national regulations). The stock is managed according to the FIFO principle. Deliveries are made exclusively to pharmacies and wholesalers. The company keeps records of its customers' confirmation that the goods have been received in good condition.
6.	Traceability ensured <i>Rückverfolgbarkeit gewährleistet</i>	☒ compliance confirmed ☐ recommendation ☐ deviation ☐ n/a, justification:	Upon receipt of goods, the batch number, quantity and use-by date of the goods delivered are recorded in the IT system. Upon delivery, a delivery note is generated with the batch number. This enables the goods to be traced.
7.	Complaint handling process available <i>Prozess zur Bearbeitung von Beschwerden vorhanden</i>	☒ compliance confirmed ☐ recommendation ☐ deviation ☐ n/a, justification:	In the event of a complaint about goods, an investigation is carried out, which is documented in a report, including photographs where necessary. In the event of damaged goods, the customer receives a replacement delivery. The manufacturer is informed.

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8.	Recall process available Rückrufprozess vorhanden	☒ compliance confirmed ☐ recommendation ☐ deviation ☐ n/a, justification:	Recalls are ensured, where necessary, through batch traceability.
9.	Change management process available Änderungsmanagement-Prozess vorhanden	☒ compliance confirmed ☐ recommendation ☐ deviation ☐ n/a, justification:	The manufacturer will be informed of any changes

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10.	Procedure for CE marking verification Verfahren zur Überprüfung der CE-Kennzeichnung	☒ compliance confirmed ☐ recommendation ☐ deviation ☐ n/a, justification:	Inspection as part of the incoming goods check, on a random basis
11.	Procedure for DoC verification Verfahren zur Überprüfung der Konformitätserklärung	☒ compliance confirmed ☐ recommendation ☐ deviation ☐ n/a, justification:	The DoC is filed in the documentation and forms part of the national registration.
12.	UDI verification process Verfahren zur Überprüfung der UDI	☐ compliance confirmed ☐ recommendation ☐ deviation ☒ n/a, justification:	The company works exclusively with EAN codes. Additionally, in CZ, the PDK code (Czech: PharmData kód) serves as a central, standardised identification code used by manufacturers, distributors, hospitals and pharmacies
13.	Manufacturer labeling verification process Verfahren zur Überprüfung der Herstellerkennzeichnung	☒ compliance confirmed ☐ recommendation ☐ deviation ☐ n/a, justification:	Inspection as part of the incoming goods check, on a random basis
14.	Instructions for Use verification process Verfahren zur Überprüfung der Gebrauchsanweisung	☒ compliance confirmed ☐ recommendation ☐ deviation ☐ n/a, justification:	Inspection as part of the incoming goods check, on a random basis

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15.	Nonconformity reporting process Verfahren zur Meldung von Nichtkonformitäten	☒ compliance confirmed ☐ recommendation ☐ deviation ☐ n/a, justification:	Non-conformities are reported to the manufacturer.
16.	Complaint handling process Verfahren zur Bearbeitung von Beschwerden	☒ compliance confirmed ☐ recommendation ☐ deviation ☐ n/a, justification:	Complaints are reported to the manufacturer.
17.	FSCA / FSN support process Unterstützungsprozess durch Sicherheitskennzeichnungsmaßnahme im Feld / Sicherheitsanweisung im Feld	☒ compliance confirmed ☐ recommendation ☐ deviation ☐ n/a, justification:	FSCA / FSN are ensured, where necessary, through batch traceability.
18.	Traceability maintained Rückverfolgbarkeit gewährleistet	☒ compliance confirmed ☐ recommendation ☐ deviation ☐ n/a, justification:	see 8.
19.	Storage and transport controls documented Kontrollen bei Lagerung und Transport dokumentiert	☒ compliance confirmed ☐ recommendation ☐ deviation ☐ n/a, justification:	see 5.
20.	Authority cooperation process Verfahren zur Zusammenarbeit mit den Behörden	☒ compliance confirmed ☐ recommendation ☐ deviation ☐ n/a, justification:	The company works closely with the national authority responsible, which carries out regular inspections. Furthermore, the distributor and the products it sells must be registered with the authority; this is a regulatory requirement for distribution in the Czech Republic.
21.	Regulatory responsible person identified Beauftragte Person für die Einhaltung der Vorschriften benannt	☒ compliance confirmed ☐ recommendation ☐ deviation ☐ n/a, justification:	Marie Krabcová (pharmaceutical manager)

Der Hersteller muss die Zertifizierung gemäß dieser Liste der Anforderungen vorlegen, wenn dies erforderlich ist. Prozesse etabliert und notwendige regulatorische Kenntnisse vorhanden sind.

- ☐ The distributor does not currently hold certification in accordance with the relevant standards, but has demonstrated an understanding of regulatory requirements. The necessary processes are in place.
Der Vertreiber hält aktuell keine Zertifizierung gem. relevanter Normen, konnte jedoch ein regulatorisches Verständnis zeigen. Die erforderlichen Prozesse sind etabliert.
- ☐ The distributor does not currently hold certification in accordance with relevant standards, but was able to demonstrate a basic understanding of regulatory requirements. The necessary processes are sufficiently established.
Der Vertreiber hält aktuell keine Zertifizierung gem. relevanter Normen, konnte jedoch ein grundlegendes regulatorisches Verständnis zeigen. Die erforderlichen Prozesse sind hinreichend etabliert.
- ☐ The distributor was unable to demonstrate the implementation of the necessary requirements. Measures to rectify non-conformities must be completed prior to supply.
Der Vertreiber konnte die Implementierung erforderlicher Anforderungen nicht zeigen. Vor der Belieferung müssen Maßnahmen zur Behebung von Abweichungen abgeschlossen sein.

Summary of deviations | Zusammenfassung der Abweichungen:

No. of recommendations Anzahl Empfehlungen	No. of deviations Anzahl Abweichungen
0	0

Follow-up | Nachverfolgung:

☒ No follow-up is required | Es ist keine Nachverfolgung erforderlich

7 Certification decision | Entscheidung unter der Zertifizierung

- The supplier is | Der Lieferant ist
- ☒ approved | genehmigt
- ☐ approved with conditions (see above) | genehmigt unter Auflagen (s.o.)
- ☐ not approved | nicht genehmigt

Function	Name	Signature	Date
Audit lead	Julia Gettmann		28.08.2026
QA/RA	Francesca Bruno		28.08.2026