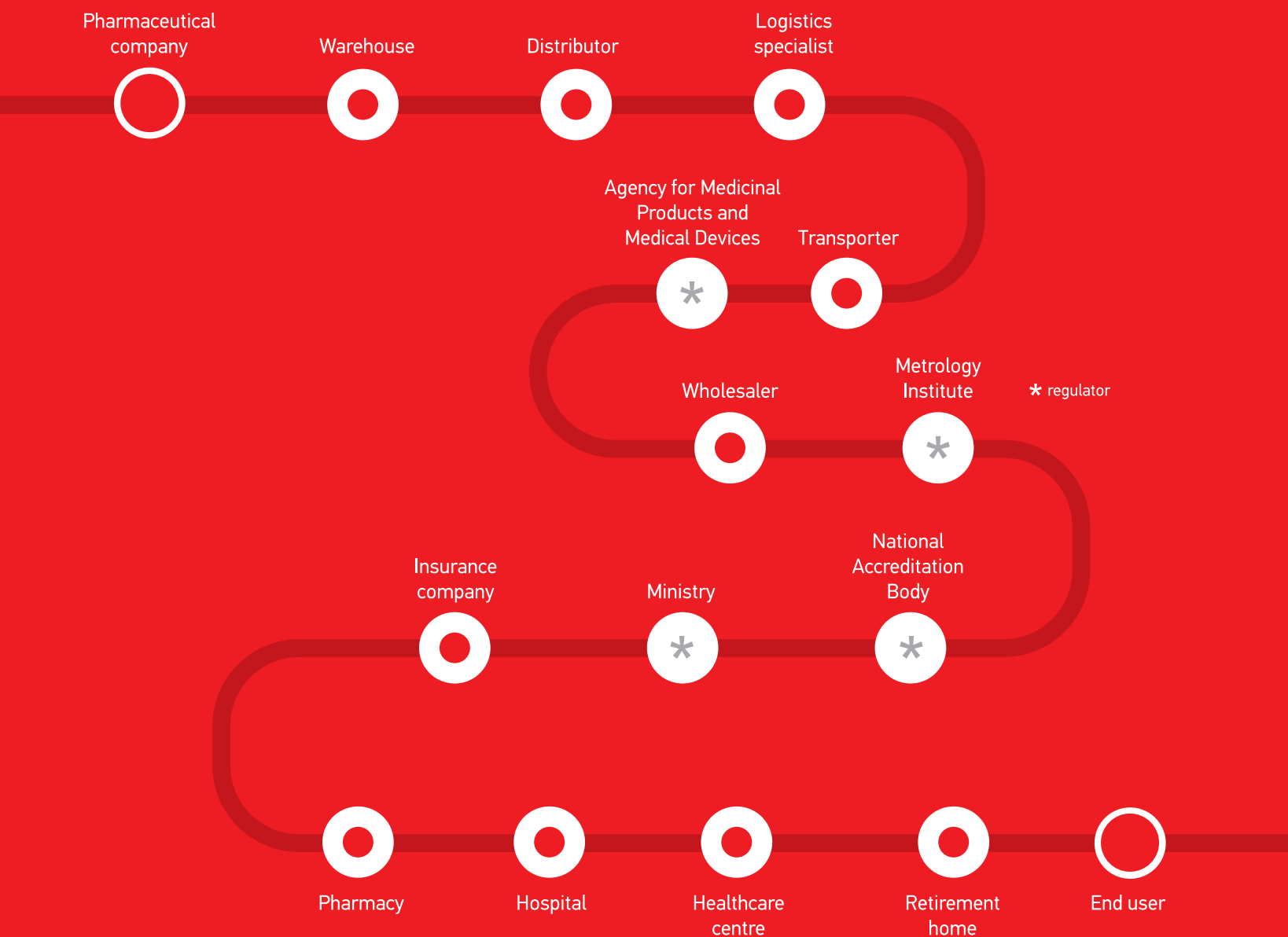


 **PHARMACERTIFICATE**

By LOTRIČ Metrology



WE MEASURE. YOU GROW.



#### READY

Download LOTRIČ AR for free from your Play Store/App Store.



#### STEADY

Scan the whole page.



#### GO

Watch it come to life!

# YOU CHOSE TO CARE. THANK YOU.

- You are contributing to the greater safety of transported goods and reducing the costs which would result from inappropriate transport.
- You enable mobility, which saves time and money.
- You provide yourself and your partners less administration and faster logistics.



21 days

Medicinal products can travel for 21 days and more.

€ 1  
million

The value of the transport of pharmaceutical products on average amounts to € 1,000,000.

0.14 %

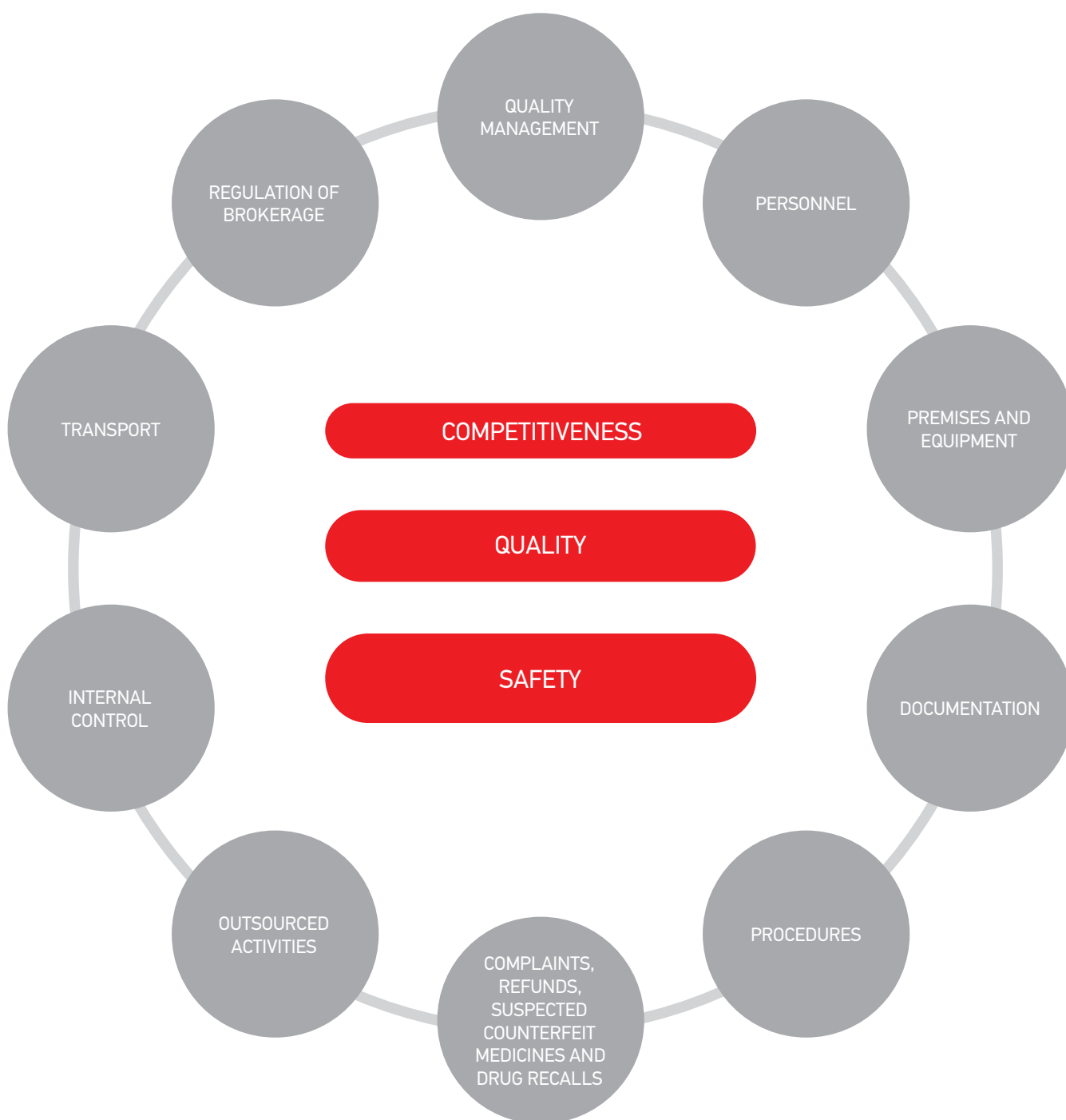
The cost of obtaining the full PHARMA certificate amounts to only 0.14 % of the value of the consignment.

# GOOD DISTRIBUTION PRACTICE

In order to deliver:

**COMPETITIVENESS, QUALITY and SAFETY**

we need to control the elements that significantly impact the quality of the distribution channel.



# COMPETITIVENESS

Choose a custom-tailored certificate  
COMPLIANT WITH GDP REQUIREMENTS

## SEASONAL PHARMA CERTIFICATE –



- Accredited calibration of installed temperature sensors.
- Accredited summer or winter mapping (second season mapping) in two temperature regimes.
- Furnishing vehicles with PHARMA labels.
- **Issue of PHARMA CERTIFICATE.**

## FULL PHARMA CERTIFICATE



- Accredited calibration of installed temperature sensors.
- Accredited summer and winter mapping in two temperature regimes.
- Furnishing vehicles with PHARMA labels.
- **Issue of PHARMA CERTIFICATE.**

## FULL PHARMA CERTIFICATE + ATP CERTIFICATE



- Accredited calibration of installed temperature sensors.
- Accredited summer and winter mapping in two temperature regimes.
- ATP control.
- Furnishing vehicles with ATP and PHARMA labels.
- **Issue of ATP CERTIFICATE and PHARMA CERTIFICATE.**

## TYPE- COMPLIANT PHARMA CERTIFICATE

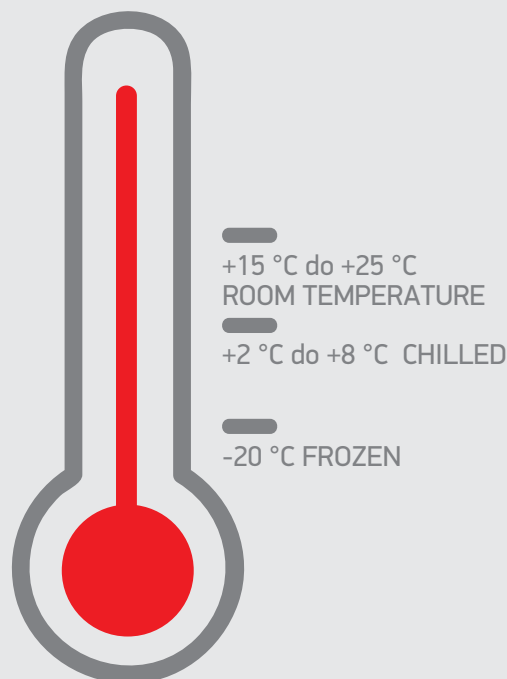


- Assessment of conformity of installed insulated box.
- Assessment of conformity of installed thermal devices (aggregate).
- Furnishing vehicles with PHARMA labels.
- **Issue of PHARMA CERTIFICATE.**

## COPY OF PHARMA CERTIFICATE



- Copy of the valid PHARMA CERTIFICATE issued by LOTRIČ Metrology.
- Updating vehicle and owner data.
- Furnishing vehicles with PHARMA labels.
- **Issue of PHARMA CERTIFICATE.**



# The certificate that counts!

## Measurements in different temperature regimes:

+15 °C to +25 °C ROOM TEMPERATURE  
+2 °C to +8 °C CHILLED  
below -20 °C FROZEN

## Summer/winter seasonal variations

## Open door test

<b>LOTRIČ®</b> METROLOGY		Številka certifikata certificate number 152-15-21-1	
<b>PHARMA CERTIFIKAT</b> PHARMA CERTIFICATE			
naročnik applicant	PODJETJE, d.o.o. Ulica meroslovja 1, 1000 Ljubljana		
imetnik owner	PODJETJE, d.o.o. Tehnična ulica 21, 2000 Maribor		
lokacija location	LIKACIJA CELJE Trg meroslovja 45, 3000 celje		
oprema equipment	Temperaturno nadzorovano vozilo Temperature controlled vehicle		
identifikacijska številka vozila (VIN) vehicle identification number (VIN)	WSMD00000002100000		
registracijska številka registration number	CE LM-123		
proizvajalec manufacturer	izolativna nadgradnja insulated box SCHMITZ CARGOBULL	hladilna enota refrigeration appliance THERMO KING	zapisovalnik temperature temperature recorder CARRIER
tip type	SKO 24	SLX6 SPECTRUM	Data cold 300
	številka nadgradnje insulated box number 0000012	številka hladilne enote refrigeration appliance number 7654321	številka zapisovalnika temperature recorder number 0025874001
datum izvedbe date of performance 10. 08. 2021		datum odobritve date of approval 11. 08. 2021	
izvedel performed by Marko Fon Internally digitally signed		odobril approved by Primož Valner odgovorna oseba responsible person	
 			
<b>PHARMACERTIFICATE</b>			
Ta dokument se sme objavljati ali posredovati le v celoti. Verodostojnost podpisa se lahko preveri v elektronski obliki dokumenta. This document may be published or forwarded only in full. Signature validity can be verified in electronic version.			
LOTRIČ Meroslovje d.o.o., Selca 143, 4227 Selca T +386 4 517 07 00, F +386 4 517 07 01, E info@lotric.si, W www.lotric.si			
v1.0		stran 1 / 4	

## Certificate holder and vehicle owner demonstrate that the inspected vehicle complies with:

- Guidelines of the Good Distribution Practice (GDP);
- Requirements of national rules relating to the transportation and distribution of medicinal products;
- Requirements of European Pharmacopoeia, Ph. Eur.;
- Requirements of the United States Pharmacopeia (USP);
- Recommendations of the World Health Organization (WHO).

## Compliance is demonstrated by:

**MAPPING** in vans and heavy goods vehicles is carried out in accordance with the requirements of the client or the manufacturer of the medicinal products.

Scope of vehicle control according to the **ATP** agreement.

## CALIBRATION OF TEMPERATURE SENSORS

Maintenance of cold chain on the route of foodstuffs and medications to the end user.

[illegible]

**LOTRIC<sup>®</sup>** METROLOGY

**(SLO)**

certifikat posrednik  
151-343-20-1

# ATP CERTIFIKAT ATP CERTIFICATE

Izdati v skladu s Sporazumom o mednarodnem pregledu posredniških služb in s specialnih volov za njihovo pravo (ATP),  
based pursuant to the Agreement on the International Certificate of Periodicals Functionality and on the Special Agreement for the Use of  
for Such Certificate (ATP).

1. **agencija**  
**equipment**

Mehanična hišna  
Mechanically refrigerated  
LOTRIC Metrology Ltd, Seka 163, SI-4207 Seka, Slovenia

2. **organi**  
**issuing authority**

Poljski inštitut  
Sens-metro

3. **agencija**  
**operator**

PL 123 144

4. **registrirana številka**  
**registration number**  
Ident. št. vsakega ena  
vehicle ident. no. vseh  
vehicles and  
document by

WMS40000000012345  
SCHWETZ CARBORELL AG

5. **izdatnik**  
**issuing body**

tip  
type

SKO 26

proizvajalec  
manufacturer

SCHWETZ CARBORELL AG

letnik  
year of manufacture

2018

registrirana  
number

000000000000000000

6. **izdatnik ali operater**  
**owner or operator**

PODJETJE d.o.o., ulica merosništva 1, 1000 Ljubljana

7. **prejeto**  
**submitted by**

PODJETJE d.o.o.

datum izdatja  
date of inspection

14.08.2021

izvedel/  
inspector performed by

PODJETJE d.o.o.

datum zadnjega  
date of approval

17.08.2021

sig. za vs. resp. for all  
Jaz, tisk.  
signature, master  
responsible person

potrdilo organ  
the competent authority

LOTRIC Metrology d.o.o. po Predstavni Agenciji za varnost pravnih št. 37.17.80.2012/26.  
LOTRIC Metrology Ltd. by Order of the Public Agency for the 37.17.80.2012/26.

Številčkanje in vsebina dokumenta so predmetne in veljajo. Vsebinsko pregledano in izdano po elektronski poti dokumenta.  
This document may be checked and forwarded only by e-mail. Signature validity can be verified in electronic version.

atp-cp 2/2

**LOTRIČ** METROLOGY

Issued certificate  
 number  
 Z50-1210-21-1

**Merited results (before step3)**  
**measured results (in step)**

reference material reference value C13	practical material reference value C13	practical error C13	measured magnitude uncertainty C13	SDP part C13
1) base signal: signal of 1st 2nd and 3rd				
0.0	0.0	0.0	0.1	0.5 ✓
10.0	10.0	0.0	0.1	0.5 ✓
30.0	30.1	0.1	0.2	0.5 ✓
2) base, middle, signal of 1st 2nd and 3rd				
0.0	0.1	0.1	0.1	0.5 ✓
10.0	10.1	0.1	0.1	0.5 ✓
30.0	30.1	0.1	0.2	0.5 ✓

CERTIFICAT O KALIBRACIJI CALIBRATION CERTIFICATE

str. 2 od 2

1 / 4

- |  |  |   |
|--|--|---|
| <ul style="list-style-type: none"> <li>• While the vehicle is stationary or on the road.</li> <li>• In full and/or empty vehicles.</li> <li>• In representative conditions, where seasonal fluctuations must be considered.</li> <li>• Issue of accredited calibration certificate.</li> </ul> | <ul style="list-style-type: none"> <li>• Inspection of isothermal properties of vehicle in use.</li> <li>• Inspection of performance of thermal devices in use.</li> <li>• Equipping the vehicle and/or trailer vehicle with internationally valid ATP labels.</li> <li>• Issue of internationally valid ATP certificate.</li> </ul> | <ul style="list-style-type: none"> <li>• Calibration of the temperature recorder in compliance with standards EN 12830, EN 13485 and EN 13486.</li> <li>• Calibration within the range in which monitoring is carried out.</li> <li>• Recommended calibration in at least three temperature points (for all temperature probes of the recorder).</li> <li>• Issue of the accredited calibration certificate.</li> </ul> |
|--|--|---|

**LOTRIČ<sup>®</sup>** METROLOGY

posiljal nasvetov  
smeru posilja

Številka certifikata  
certificate number  
251-357-21-1

**legenda legend**

Pozicija: 1, 2, 5, 6, 9, 10, 11 in 12 razporedjeni spredaj po krovu stranske naprave.  
Positions: 1, 2, 5, 6, 9, 10, 11 and 12 placed at top side corners.  
Pozicija: 3, 4, 7, 8, 11, 12, 15 in 16 razporedjeni na krovu stranske naprave.  
Positions: 3, 4, 7, 8, 11, 12, 15 and 16 placed on top side corners.  
Pozicija: 17, 18 in 18 razporedjeni vzdolž stranice.  
Positions: 17, 18 and 18 placed along the carrier.  
Pozicija: 18 in referenčni točki.  
Position: 18 in reference point.

CERTIFIKAT O KALIBRACIJI CALIBRATION CERTIFICATE

stran page 2 of 4

# SAFETY

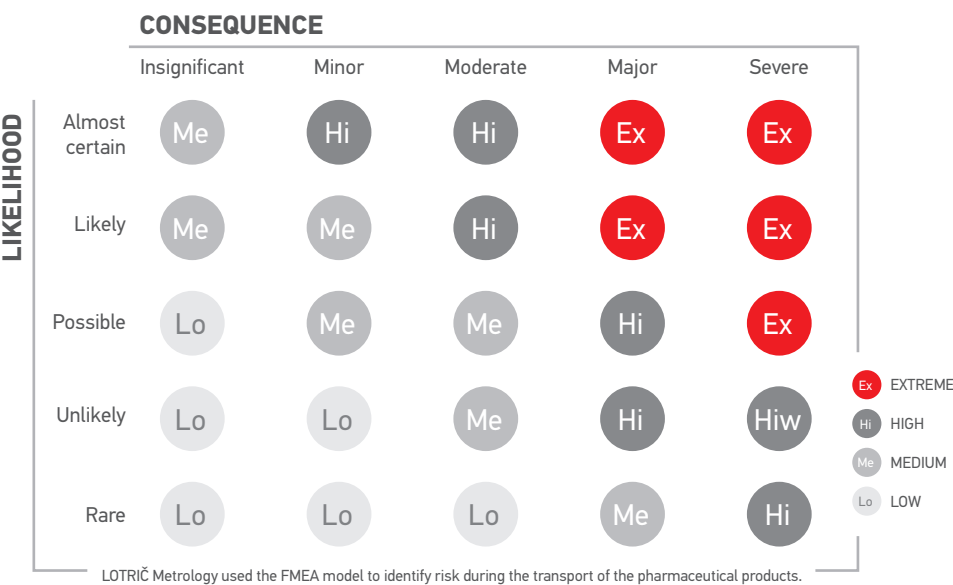
## QUALIFICATION

Qualification is a documented procedure of testing and certifying that a vehicle and installed equipment functions properly, and leads to the safe transport of the consignment:

- in accordance with the Good Distribution Practice guidelines,
- and in accordance with FDA (Food and Drug Administration) requirements.

## MANAGE RISK OF THE SUPPLY CHAIN

Risk assessment reduces costs and increases efficiency



DQ

**Design Qualification**  
Verifying the suitability of the enclosed documentation – specifications with the actual condition of the unit which is the subject of the inspection, in accordance with the Good Distribution Practice guidelines.

IQ

**Installation Qualification**  
Qualification during the installation of the equipment which is used to certify, in a documented manner, that the equipment which is the subject of the qualification was designed and installed in accordance with the user's specifications.

OQ

**Operations Qualification**  
Qualification where we demonstrate, on the basis of the performed measurements, that the installed equipment functionally and repeatedly complies with the defined requirements.

PQ

**Performance Qualification**  
Qualification where, on the basis of the tests performed (on a sample), we assess the suitability of the performance of the installed equipment.



# QUALITY

**ORDER  
ACCEPTANCE**

Your data is recorded and prepared for further processing.

**LOCATION**

We agree upon the location which suits you best.

**DOCUMENTS**

We review the documents for the purpose of carrying out measurements.

**Information about the insulated box**

- serial number
- type

**Information about the vehicle**

- registration certificate
- type-approval certificate
- prior ATP certificate

**Information about the cooling/heating unit (thermal appliance)**

- serial number
- type
- manufacturer
- year of manufacture



After we receive the required documents, you are only 5 days from receiving the PHARMA CERTIFICATE.

**CALIBRATION**

**MAPPING**

**ATP CONTROL**

  
**CERTIFICATE**

After the measurement process is completed, the technical staff perform the calculation and generate the certificate using the software.

# EXACTUM

*Contributing to the greater safety of transported goods*

## WHERE WE MEASURE:

- in production areas,
- in warehouses,
- during transport.

## WHAT WE MEASURE:

- temperature,
- relative humidity,
- levels of CO<sub>2</sub> in the atmosphere,
- illuminance,
- other parameters of your choice.

## HOW IT WORKS:

- continuous automatic measurement and access to all data in one place;
- immediate warning and reaction via SMS and e-mail;
- organized database, reporting and archiving;
- wired and wireless.

## HOW DOES IT WORK?

EXACTUM<sup>®</sup> automatically captures and stores measured values from measuring points equipped with sensors. If limit values are exceeded, the system sends a warning. The automatic generation of reports, and having all data collected in one place, make your job easier and save you precious time.

Compliance with GXP, CFR 21 Part 11, EU GMP Annex 1, calibration according to ISO 17025.

## EXACTUM<sup>®</sup> enables



Monitoring of measurements in real time.



Setting of limit values, delays and alarm recipients.



Alerts via SMS and/or E-mail.



Access via web browser.



sensors with wireless connection.



Automatically generated reports.



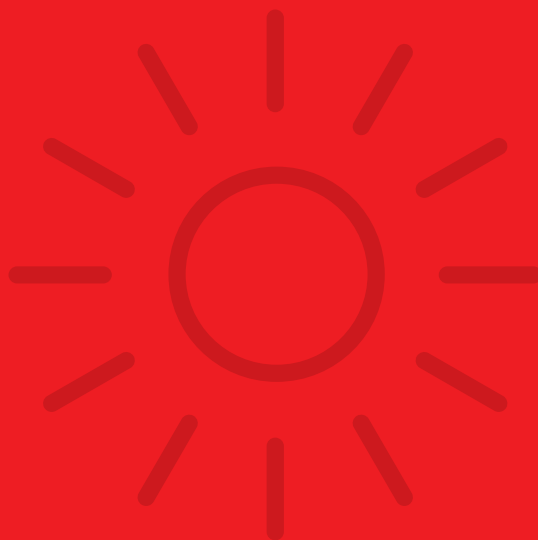
Audit trail.

## EXACTUM Cloud: easy data access

All you need to access the data is internet access and a smart device such as a phone, tablet or laptop. EXACTUM Cloud can be accessed by an unlimited number of users, each of whom has assigned access rights and personal settings for different locations. Each user can also set personalised alarms. The system is updated automatically and allows data to be exported in .xlsx, .pdf or .png formats. The data is protected in accordance with international standards.



**The solution that allows you to manage risks on the route of distribution, and which can be your competitive advantage.**



# ≡ PHARMACERTIFICATE

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By LOTRIČ Metrology





# LOTRIČ

METROLOGY

WE MEASURE. YOU GROW.

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