THERMO KING
PHARMASOLUTIONS
GDP COMPLIANT

Ensuring Pharma Cold Chain Compliance

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THERMO KING

Industry statistics indicate that:

25%

… of vaccines reach their destination in a degraded state because of incorrect shipping.

30%

… of scrapped sales at pharmaceutical companies can be attributed to logistics issues.

20%

… of temperature-sensitive health care products are damaged during transport due to a broken cold chain.

0.5%

… of transported goods are damaged during transport through non-compliance to temperature guidelines.

Source: World Health Organization (WHO), Parenteral Drug Association (PDA) and other industry estimates

How can Thermo King improve these statistics?

BOLDLY CHALLENGING WHAT IS POSSIBLE

Trane Technologies is a **global climate innovator** advancing sustainability through our brands Trane® and Thermo King®, which bring efficient and sustainable climate solutions to buildings, homes and transportation.

TRANSPORT REFRIGERATION

THERMO KING FRIGOBLOCK

COMMERCIAL HVAC

TRANE Thermocold ice cool energy AL-KO QUALITY FOR LIFE MTA

About Thermo King – Product Categories

THERMO KING PHARMASOLUTIONS GDP COMPLIANT

TRAILER

TRUCK

DIRECT DRIVE

ELECTRIC

AIR

BUS & RAIL HVAC

MARINE

STORAGE

World leader in transport temperature systems

Thermo King Locations

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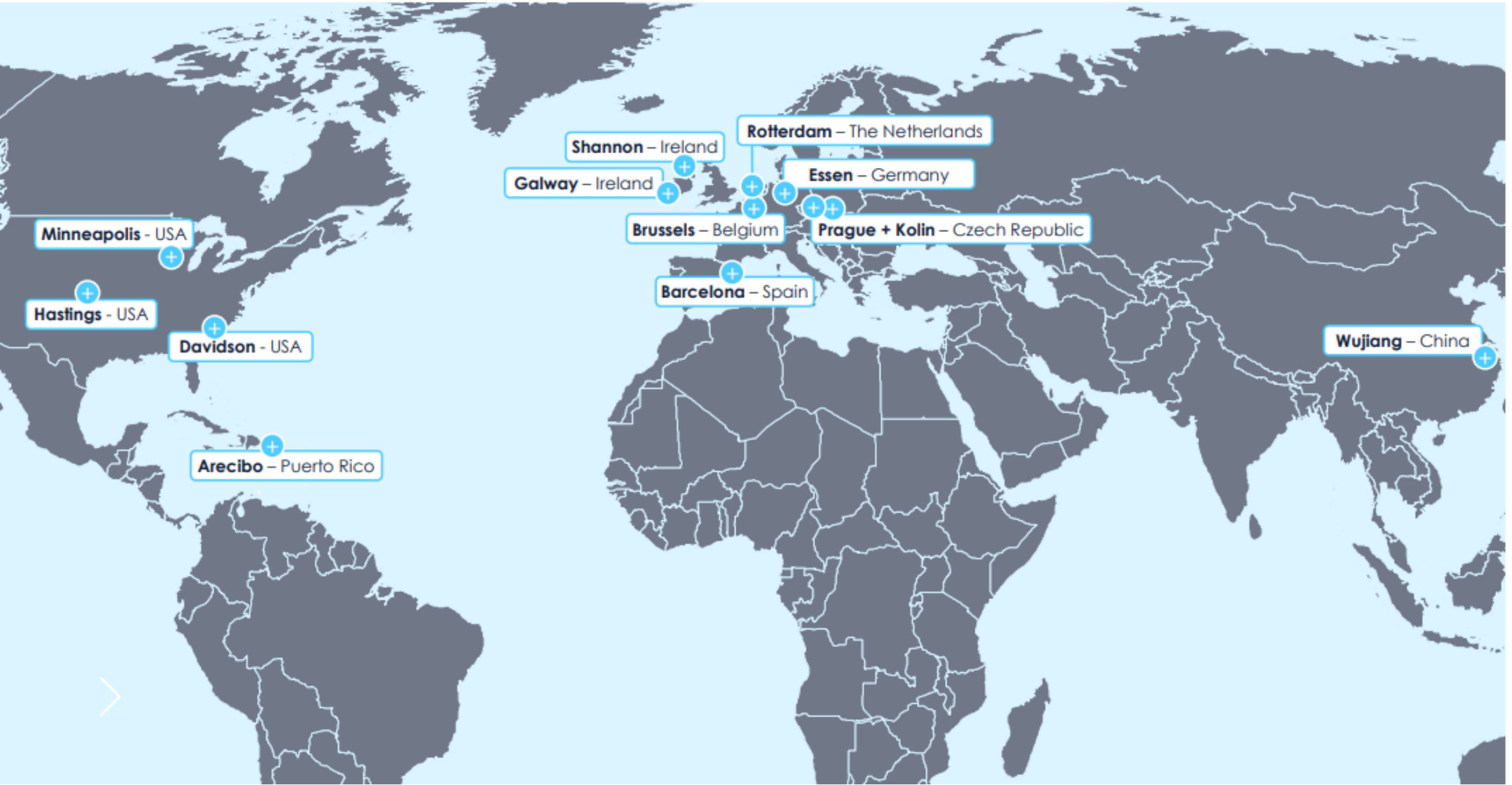

THERMO KING

DIGITAL SOLUTIONS AND SMART CONNECTIVITY

- **LOAD MONITORING**
- Digital solutions to monitor and adjust temperatures during transport

SAFETY & QUALITY REPORTS

Reports available to comply to cargo safety and hygiene protocols

MAXIMIZED UPTIME

track vehicle and cargo regardless of location, 24/7

TEMPERATURE CONTROL

Tight temperature control mechanism to prevent spoilage during transport

THERMO KING

END-TO-END TEMPERATURE-CONTROLLED TRANSPORT AND STORAGE SOLUTIONS ACROSS THE COLD CHAIN

AIR

OCEAN

ROAD

STORAGE

TRACEABILITY

Our Transport Solutions

THERMO KING PHARMASOLUTIONS GDP COMPLIANT

Thermo King Road, Air and Marine Transport Solutions

Thermo King Long Haul, City and Last Mile Transport Solutions

Pharmaceutical production facility

Distribution center or fulfillment facility

Hospitals , medical and test centers , doctors , patient

Thermo King offers refrigeration solutions for every step in the distribution chain

Thermo King PharmaSolutions

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PHARMASOLUTIONS
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A full suite of services to manage risks during pharmaceutical transport

INCLUDES

- GDP protocol
- GDP qualified portfolio of equipment
- Real-time tracking, monitoring and fleet management
- Service offering: PharmaAssist
- + 500 Service points in Europe for instant assistance - +900 Wordlwide
- Training services to enable supply chain compliance

Thermo King GDP protocol

THERMO KING PHARMASOLUTIONS GDP COMPLIANT

GDP Protocol in 4 stages aligned with the EU directives
GDP CERTIFIED UNITS FOR: road, marine, intermodal transport

1

Design Qualification (DQ)

2

Installation Qualification (IQ)

3

Operations Qualification (OQ)

4

Performance Qualification (PQ)

THERMO KING PHARMASOLUTIONS

GDP Qualification of equipment with temperature controlled unit for the transport of pharmaceutical products

Temperature Controlled Unit

Unit Manufacturer: THERMO KING **Serial number:**
Type: Magnum Plus **Container ID number:**

GDP Validation Certificate Nr: GDP-TK_CT-ST_2019.05_E0GM001050

GDP validation date: 2019-05-19
GDP expiration date: 2022/05

This document certifies that the mentioned equipment has been qualified and validated GDP Pharma compliant.

In line with the EU Guidelines of Good Distribution Practices of medical products for human usage (GDP), and Good Manufacturing Practices (GMP)

The **Thermo King GDP validation protocol** covers the four stages of qualification of the GDP guideline. This was validated by an independent pharmaceutical consultant company, **Baggerman Farma Consult.**

The installation qualification (IQ) of the mentioned equipment was conducted successfully, and thus conforms to the configuration laid out in the master qualification documents:

- Design Qualification (DQ): GDP_TK_DQ_CT_ST
- Installation Qualification (IQ): GDP_TK_IQ_CT_ST
- Operational Qualification (OQ): GDP_TK_OQ_CT_ST
- Performance Qualification (PQ): GDP_TK_PQ_CT_ST

Some modifications made to the equipment's configuration may cancel the validity of this document.

Example of Certificate

Baggerman Farma Consult	Thermo King	Trane Technologies
J. E. Vaessen	Roland Duquesne	Daniel Žmola
CEO and Pharmacist	Director PharmaSolutions Vertical Market EMEA	Director Trane Technologies Engineering and Technology Center Prague

BAGGERMAN FARMA CONSULT BV THERMO KING ETC PRAGUE

Installation & Operation Qualification (IQOQ)

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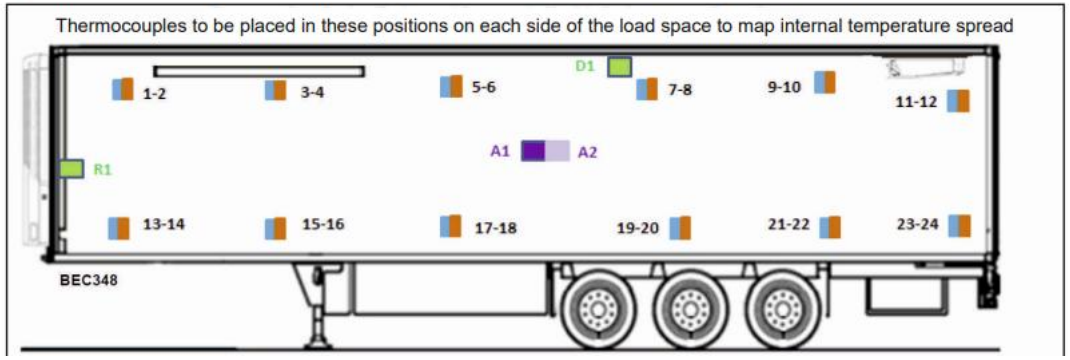
- Performed by Thermo King dealer that installs the cooling unit
- The vehicle (refrigeration unit & vehicle body) is inspected to confirm to the design qualification
- Photographic evidence is requested

- 3-point temperature test is performed and documented
- 20-25 thermo coupling locations in the box
- Data loggers are calibrated
- Unit performance is tested

Single Temperature Thermocouple Locations

Figure 3. Thermocouple Locations

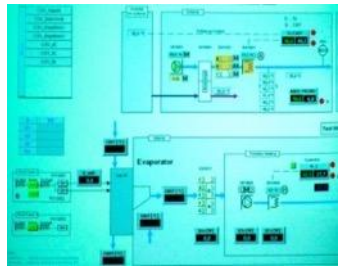


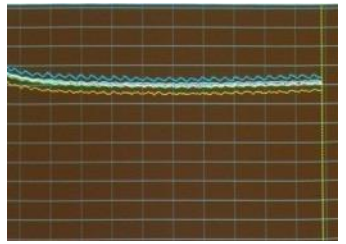
Performance Qualification

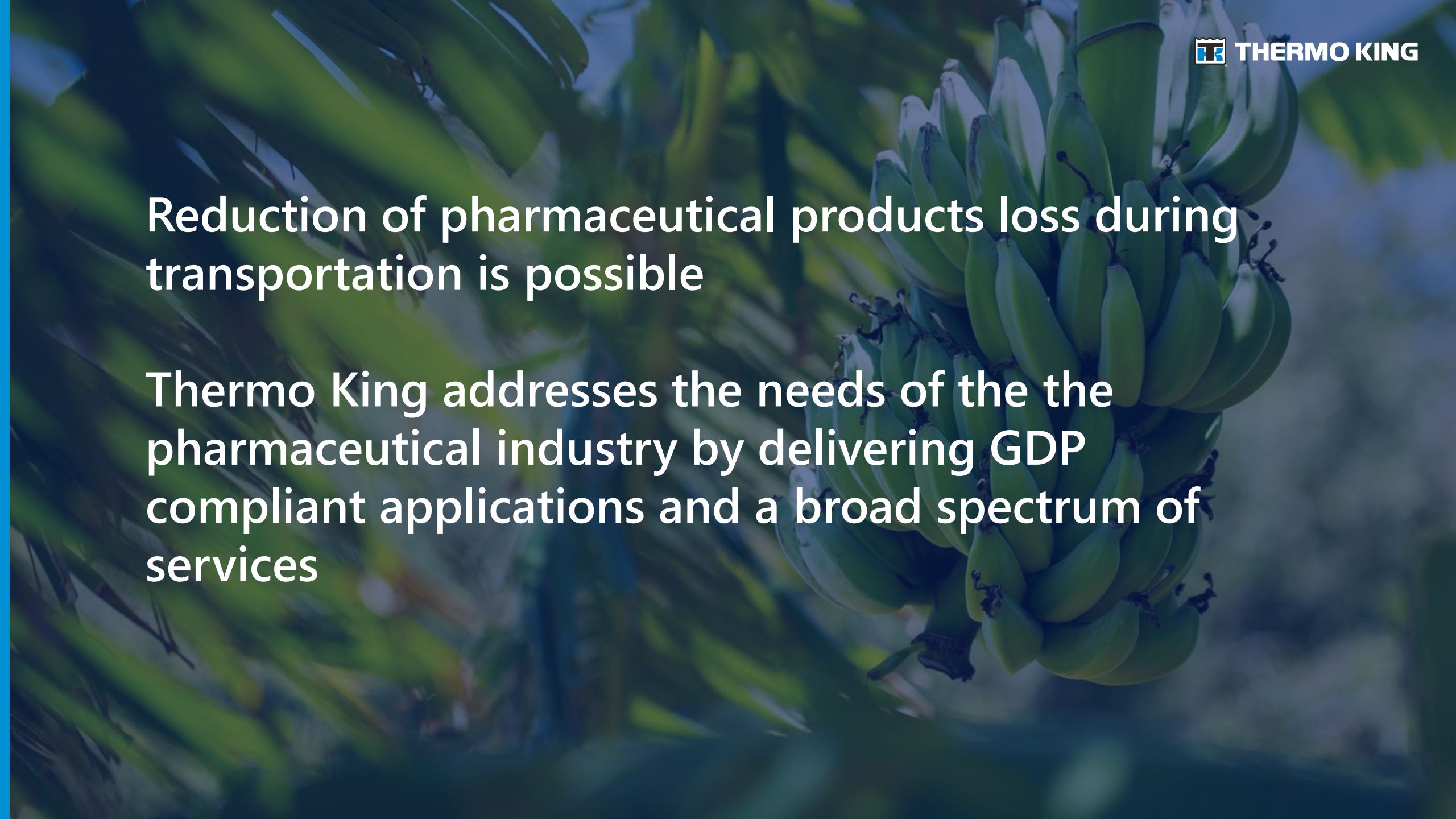
Test conducted in a controlled climatic chamber

KEY FEATURES

- Testing temperature range from -30°C to +60°C
- Tests conducted in an Independent Testing Technology Center (ISO and ATP certification authorized)







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Reduction of pharmaceutical products loss during transportation is possible

Thermo King addresses the needs of the the pharmaceutical industry by delivering GDP compliant applications and a broad spectrum of services

THANK YOU!
THERMO KING
TRANE
TECHNOLOGIES