

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

<u>Temperature Controlled Unit</u>		<u>ATP Certified Body</u>	
Unit Manufacturer:	THERMO KING	Body Manufacturer:	SCHMITZ
Type:	SLXi Spectrum 2 50 S3	Body Number:	5255790
Serial number:	GLW1281961	Chassis Number:	WSM00000005255790
		Vehicle Identification plate:	PB9963EB

GDP Validation Certificate Nr: GDP-TK_TR-MT_2021.02_GLW1281961

GDP validation date: 2021-02-11

GDP expiration date: 2024/02

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_TR-MT
• Installation Qualification (IQ):	GDP-TK-IQ_TR-MT
• Operational Qualification (OQ):	GDP-TK-OQ_TR-MT
• Performance Qualification (PQ):	GDP-TK-PQ_TR-MT

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



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