



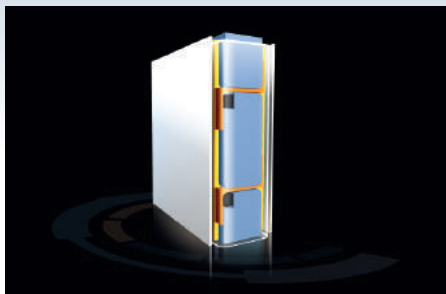
PHARMA
SAFE+

Lamberet cold transport,
also means healthcare.

PHARMACEUTICAL GDP COMPLIANT
Good Distribution practice of medicinal
products for human use, European
Commission (OJ C 343/1, 23.11.2013)



The transportation of healthcare products has benefited from the specialist sector approach adopted by Lamberet. The Lamberet "Pharmasafe+" product certification is dedicated to the "Good Distribution practice of medicinal products for human use" guide (BPD / GDP). This guarantees that your equipment meets the criteria specified for the transportation of healthcare products requiring special conditions such as thermosensitive substances, as defined by the European Commission (OJ C 343/1, 23.11.2013) and by the Agence nationale de Sécurité du médicament [National Agency for Drug Safety] (decision of the ANSM director, 20/02/2014- OJ 25/03/2014 and its appendix BO No. 2014/9 bis., dated 17/06/2014). The specifications encompassed by Pharmasafe+ have been subject to the necessary conformity and qualification tests required by the qualified certifying bodies for each of the domains concerned. This certification is available for all the eligible ranges of Lamberet vehicles.



Performance of the insulated cell and the refrigerated unit: Lamberet offers you the most effective insulation system, formed of composite materials configured in a complex application. Each cell has an insulation coefficient attested by an ATP "reinforced insulation" quality qualification, with reference to the certificate type. Your insulated cell carries a guarantee of conformity and repeatability in relation to the type tested, through our ISO 9001 certification audited each year by Intertek. Finally, the restriction of light colours on the outside limits the negative effect of heat radiation. The conformity of the refrigeration selected for your pharmaceutical configuration is attested through testing and an ATP report reflecting its actual performance.



Conformity of the device (cell + unit): in the context of the Pharmasafe+ certification, Lamberet applies an added safety coefficient to the insulated cell and unit assembly, with reference to the calculations relating to the equipment concerned, in a personalised thermal report:

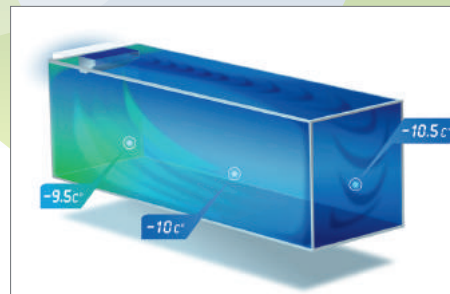
- Class A (positive cooling): > 4.5
- Class C (negative cooling): > 2.5

An ATP technical attestation of conformity issued by the competent national authority is issued with each vehicle.



Alarm and safety mechanisms: every temperature swing or damage caused to drugs during transport must be notified to the wholesale distributor and to the recipient of the drugs, in accordance with the BDP / GDP directives. In order to achieve this, the Pharmasafe+ certification is based upon the presence of an alarm mechanism detectable at all times by the driver or their operations manager. Any initial temperature deviation in real time / from the set point is transmitted via a telematics alert system and/or reversing thermometer incorporating a flash.

The safety of goods is further reinforced by the presence of a redundant sealing system. With duplication of the original seals, a mechanical or electronic code controlled anti-theft mechanism provides a particularly reliable locking system for the load zone, which is capable of meeting the most stringent requirements of insurance companies. This system can have a third level applied with an immobiliser integrated into the vehicle's EBS in the SR2 semi-trailers. Added to a very high intrinsic level of security in the design of the doors on the SR2 and rigid chassis HD ranges (recessed locks and locking bolts, exclusive to Lamberet) this equipment is particularly suited to the transportation of medicines and drugs.



Qualification of the device: temperature mapping. In the case of use of controlled temperature vehicles, a mapping of temperatures under representative conditions must be performed, taking into account seasonal variations. Your Pharmasafe+ certification systematically includes for your system type, a mapping of temperatures according to the NF X 15-140 standard, carried out by a COFRAC approved laboratory. The purpose of this mapping is validate the conformity of the specifications to the required temperatures and to adjust the reference set points:

- $20^{\circ}\text{C} \pm 2^{\circ}\text{C}$
- $5^{\circ}\text{C} \pm 2^{\circ}\text{C}$
- $-20^{\circ}\text{C} \pm 2^{\circ}\text{C}$



Traceability requirements: the objective is to enable the user of the equipment to prove that the drugs have not been exposed to conditions that could risk compromising their quality and their integrity. In order to achieve this, the Lamberet Pharmasafe+ system systematically provides for:

- A temperature recorder compliant EN 12830
- Recorder sensors positioned in relation to the initial test mapping
- A currently valid sensor calibration certificate
- A recording frequency set at a maximum of 2 minutes
- A display system during operation.



Maintenance during the qualification period: Pharmasafe+ guarantees the initial conformity of the equipment to the 93/43/CE directive relating to the hygiene during transport requirement. Monitoring of operations requires the integration of this directive in order to preserve its validity during the period of the certificate. The equipment used to monitor the temperature in vehicles during transportation must be maintained and calibrated at regular intervals and at least once a year. The Pharmasafe + programme is subject to compliance with an annual preventive maintenance technical specification applied to the cell and the unit. The validity of the certification is attested by the publication of a certificate and the presence of reference stickers on the front external faces and internal side faces.

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