



THE QUALITY LABEL

for the equipment of the cold chain
of health products



THE EUROPEAN
REFERENCE LABEL





WHAT IS

CERTICOLD Pharma ?

CERTICOLD Pharma is a European label of conformity for the equipment of the cold chain of health products.

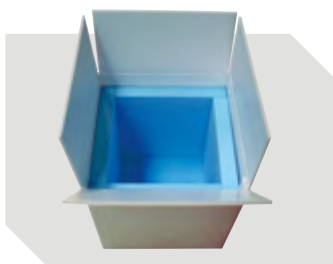
This label was created in order to:

- help professionals in the choice of equipment for transporting and storing heat-sensitive products
- recognize at European level the quality equipment used to respect the cold chain
- ensure European regulatory compliance imposed by Good Distribution Practices (GDP)
- guarantee high refrigeration performance and compliance with the temperatures required by the regulations.

LABELED EQUIPMENT

new or in use

Each equipment in the series has a label bearing the CERTICOLD Pharma logo.



Refrigerated and isothermal packaging



Refrigerating units of transport vehicle



Thermostatic chambers



Temperature recorders



Transport equipment under controlled temperature

THE ADVANTAGES

of the label



Audit of manufacturing sites

Manufacturer's quality system audit * conducted annually by an independent third-party certification body.



Tests conducted by an independent center

Isothermal and efficiency tests carried out by a COFRAC accredited laboratory on the prototype for the admission test and on a sample for the annual tests.



Self-checks continuously

Mandatory tests performed by the manufacturer and verified by an independent third-party organization during the follow-up audit.



Individual certificates by equipment

Transmitted for each labeled equipment. Markings and certificates renewable every 3 years.



European network of qualified test centers

To achieve the qualifications of vehicles Certicold Pharma new or in-service.

*Audit carried out according to a repository available on www.certicold.com

THE TESTS

carried out

FDX 15140

Temperature mapping in real scenarios

NF EN 13486

Calibration of thermometers and temperature recorders

NF S 99700

Qualification of thermal performance

ATP

Isothermal verification and calculation of the K coefficient

The guarantee of conformity
Good Distribution Practices (GPP)
for heat-sensitive health products.



HOW TO

benefit from the label?

1

LABEL APPLICATION

sent to Cemafrroid

2

AUDIT OF THE MANUFACTURER'S QUALITY SYSTEM

carried out by an independent certifying body

3

TESTS ON THE PROTOTYPE

in COFRAC accredited laboratories

4

OPINION OF THE LABELING COMMITTEE

President : Annick Demouy
(Pharmacien)

Vice-President : Guy Thomas
(Engineer)

- Competent authorities

- Users

- Cold chain experts

- Manufacturers / Suppliers

5

CERTIFICATE

issued by Cemafrroid

6

APPLYING THE CERTICOLD PHARMA LABEL

to all the equipment in the series



LEARN

more

List of certified products on
www.certicold.com

For more information, you can contact Cemafrroid, an independent organization recognized by IIR (International Institute of Refrigeration)



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? FEW definitions

Certification

Evaluation of the conformity of a product or a service with the requirements described in a repository or specifications. It gives rise to the issue of a certificate.

Qualification

Action to prove and document that a piece of equipment meets requirements specified in a standard or specification. This operation includes conducting tests.

Label

Symbol or sign of quality based on a reference document or specifications to attest to the superior quality of a product or service beyond the regulated criteria.

Accréditation

Formal recognition of an organization's competence to perform tests, calibrations, inspections, certifications, etc. In France, it is COFRAC (Accreditation French Committee) which issues accreditation to these organizations.

YOUR CERTIFIED professional

European recognition of the quality of
equipment used to store and transport
cold chain medicines.