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Contents:

1. Scope **2**
2. Normative references **2**
3. Terms and definitions **3**
4. Requirements **5**
4.1 General 5
4.2 Performance 5
4.2.1 Vaccine storage capacity *5*
4.2.2 Minimum vaccine storage compartment temperature *5*
4.2.3 Cold life *5*
4.2.4 Cold climate freeze protection life *5*
4.2.5 Conditions of use *5*
4.2.6 Design principles *5*
4.2.7 Reuse cycle *6*
4.2.8 Shape *6*
4.2.9 Lid *6*
4.2.10 Hinges *6*
4.2.11 Closure device *7*
4.2.12 Carrying device *7*
4.2.13 Primary container holding device *7*
4.2.14 Vaccine storage advice *7*
4.2.15 Stacking and handling *8*
4.2.16 Corrosion resistance *8*
4.2.17 Chemical resistance *8*
4.2.18 IP rating *8*
4.2.19 Robustness and vibration *8*
4.2.20 Coolant-packs *8*
4.3 Environmental requirements 8
4.3.1 Material properties at ambient temperatures: *8*
4.4 Physical characteristics 8
4.4.1 Overall dimensions *8*
4.4.2 Weight *8*
4.5 Interface requirements 9
4.5.1 Dimensional compatibility with coolant-packs *9*
4.5.2 Dimensional compatibility with vaccine packaging *9*
4.5.3 Compatibility with distribution method *9*
4.6 Human factors 9
4.6.1 Generally *9*
4.6.2 Portability *9*

4.7 Materials 9
4.7.1 Casing material selection *9*
4.7.2 Thermal insulation foaming agents *9*
4.7.3 PCM *10*
4.7.4 Vacuum panels *10*
4.8 Warranty 10
4.9 Servicing provision 10
4.10 Disposal and recycling 10
4.11 Instructions 10
4.12 Training 10
4.13 Verification 10
5. Packaging 10
6. In-coming inspection 11
7. Product dossier 11
8. On-site maintenance 11
9. Change notification 11
10. Defect reporting 11
Annex 1 – Label on outside of vaccine carrier 12
Annex 2 – Label on inside of lid 13
Annex 3 – Table of secondary carton sizes 14
Revision history: 15

1. Scope

This specification defines the requirements for freeze-preventive, thermally insulated vaccine carriers. Vaccine carriers are typically carried by a single health worker travelling on foot or by other means, where the combined journey time and immunization activity lasts from a few hours to a whole day. They are widely used to transport vaccines from health facilities with refrigeration to outreach sessions where refrigeration and ice is unavailable. They are also used to transport small quantities of vaccine from the lowest level storage facility – typically a district store – to fixed health facilities with or without a refrigerator. Two types of vaccine carrier are described:

- **Short range:** With a minimum +43°C cold life of 15 hours.
- **Long range:** With a minimum +43°C cold life of 30 hours.

2. Normative references

For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ASTM C1303 / C1303M-12: *Standard Test Method for Predicting Long-Term Thermal Resistance of Closed-Cell Foam Insulation.*

ASTM D999-08: *Standard Test Methods for Vibration Testing of Shipping Containers.*

ASTM D4169-09: *Standard Practice for Testing of Shipping Containers and Systems.*

EMAS: *European Union Eco-Management and Audit Scheme.*

EN 10152: *Electrolytically zinc coated cold rolled steel flat products for cold forming. Technical delivery conditions.*

EN 10169-1: *Continuously organic coated (coil coated) steel flat products - Technical delivery conditions.*

IEC 60529: Consolidated Edition 2.1 (incl. am1): *Degrees of protection provided by enclosures (IP Code).*
ISO 14001: *Environmental management systems - Requirements with guidance for use.*
ISO 20282-1: *Ease of operation of everyday products - Part 1: Context of use and user characteristics.*
ISO 9001: *Quality Management Systems – Requirements.*
ISO/IEC 17025: *General requirements for the competence of testing and calibration laboratories.*
WHO/PQS/E005/IP01: *Water-packs for use as ice-packs, cool-packs and warm-packs.*

3. Terms and definitions

Cold climate freeze protection life: The empty container is stabilized at +15°C and loaded with warm packs which have been stabilized at the same temperature for a minimum of 24 hours. The cold climate freeze protection life is measured from the moment when the container is closed until the temperature of the coldest point inside the vaccine storage compartment first reaches 0°C at a constant ambient temperature of -20°C.

Cold life: The empty container is stabilized at +43°C and loaded with coolant-packs that have been prepared in accordance with the manufacturer's coolant recharging instructions. Cold life is measured from the moment when the container lid is closed until the temperature of the warmest point in the vaccine storage compartment first reaches +10°C (after initially cooling to below +10°C during cooldown), at a constant ambient test temperature +43°C. The vaccine storage compartment must remain above 0°C.

Coolant-pack: A generic PQS prequalified water-pack complying with specification **PQS/E005/IP01**.

Cooldown: The empty container is stabilized at +43°C and loaded with coolant-packs that have been prepared in accordance with the manufacturer's coolant recharging instructions. Cooldown is measured from the moment when the container lid is closed until the temperature of the warmest point in the vaccine storage compartment first goes below +10°C, at a constant ambient test temperature of +43°C.

Freeze protection classification: The freeze protection classification is based on the number of user-interventions required to ensure freeze protection.

- Grade A, user-independent freeze protection (UIFP): when the appliance is used within its nominated temperature range (+43°C and minimum rated ambient temperature) there is no intervention required by the user to ensure that the vaccines will not be exposed to temperatures below 0°C, whatever the position of the vaccine in the vaccine compartment.
- Grade B, user-dependent freeze protection (UDFP): Even if the appliance is used within its nominated temperature range, the user must comply with a procedure provided by the manufacturer and requiring one level of intervention (e.g., the requirement to add a liner constitutes one level of intervention by the user).
- Grade C, user-dependent freeze protection (UDFP): Even if the appliance is used within its nominated temperature range, the user must comply with

a procedure provided by the manufacturer requiring more than one level of intervention.

Ice-pack: A water-containing coolant-pack frozen to a temperature between -5°C and -25°C before use, to the point where there is no remaining liquid water.

In writing: Communication by letter, fax or email.

Legal Manufacturer: The natural or legal person with responsibility for the design, manufacture, packaging and labelling of a product or device before it is placed on the market under the person's own name, regardless of whether these operations are carried out by that person or on that person's behalf by a third party.

Maximum loaded weight: The weight of a container when fully loaded with coolant-packs and vaccines with a density of 0.8 kg per litre of vaccine storage capacity.

Minimum rated ambient temperature: All containers will be tested to determine the lowest constant ambient temperature at which the vaccine storage compartment remains above 0°C. The test is carried out at +15°C unless the manufacturer specifies a lower figure.

Montreal Protocol: Montreal Protocol on Substances that Deplete the Ozone Layer.

Phase Change Material (PCM): A material, other than water, which changes state between solid and liquid or changes between two different solid crystallization states over a defined temperature range, absorbing or releasing heat during the phase change. This process is reversible and can be useful for thermal control in cold chain devices and products.

Primary container: Vial, ampoule, prefilled device, plastic dispenser, or tube containing vaccine or diluent.

Reseller: A commercial entity, licensed to act on behalf of a Legal Manufacturer, and which carries product liability and warranty responsibilities no less onerous than those carried by the Legal Manufacturer.

Secondary carton: A carton which contains a number of individual primary containers. Most countries have traditionally stored and distributed vaccines in these cartons.

User-Intervention: Any activity that is required to be executed by equipment users in order to ensure vaccine protection against freezing. Activities could include the addition of a removable liner to the vaccine carrier or the conditioning of ice-packs before placement in the carrier.

Vaccine storage capacity: The volume of the vaccine storage compartment measured with the full number of coolant-packs in place. Capacity will be published as length, width and height in centimetres and volume in litres. If the volume is not rectangular in horizontal cross-section, the capacity may be published as area in square centimetres, height in centimetres and volume in litres.

Vaccine storage compartment: The zone within an insulated container which is designated by the manufacturer as suitable for storing vaccine when the container is loaded with the full number of coolant-packs required to achieve the cold life specified in this document.

Warm water-pack: A coolant-pack typically stabilized at room temperature, up to a recommended maximum of +24°C. Warm water-packs are used for

the transport of freeze-sensitive vaccines during exposure to sub-zero ambient temperatures.

Water-pack: A flat, leak proof, plastic container, filled with tap water, complying generally with specification **PQS/E005/IP01**.

4. Requirements

4.1 *General*

Short range or long range thermally insulated vaccine carrier, with insulated lid, designed for transporting vaccines. Both rigid non-rigid and semi-rigid designs are acceptable. Typically vaccines will be loaded as loose primary containers. Larger vaccine carriers may also be used to transport secondary cartons.

The accuracy necessary for all temperature measurements and meeting of all temperature requirements is ±0.5°C.

4.2 *Performance*

4.2.1 Vaccine storage capacity

- **Short range:** Minimum 0.5 litres.
- **Long range:** Minimum 1.0 litres.

Provided the weight limits in clause 4.4.2 are not exceeded, no maximum capacity is set.

4.2.2 Minimum vaccine storage compartment temperature

The temperature inside the vaccine storage compartment must remain above 0°C during the cold life test conducted at an ambient temperature of +43°C. The temperature must also remain above 0°C during the minimum rated ambient temperature test when conducted at +15°C (or at a lower temperature specified by the manufacturer).

4.2.3 Cold life

- **Short range:** minimum 15 hours when tested at constant ambient temperatures of +43°C and +15°C (or at a lower test temperature specified by the manufacturer).
- **Long range:** minimum 30 hours when tested at constant ambient temperatures of +43°C and +15°C (or at a lower test temperature specified by the manufacturer).

For both short and long range carriers, the cooldown must not exceed 8 hours.

4.2.4 Cold climate freeze protection life

No standard set; however, performance data will be published.

4.2.5 Conditions of use

Vaccine carriers will typically be transported by foot, bicycle, light motorcycle or other road vehicle over road surfaces, including smooth tarmac, heavily perforated tarmac, rough gravel with deep corrugations, wet mud and dirt. They may also be carried by pack animals or transported in boats. Products must be designed to accommodate these conditions and the design must take account of possible long-term exposure to dust, rainfall and to high levels of direct sunlight.

4.2.6 Design principles

The design of the container should respect the following principles:

- Non-rigid and semi-rigid designs are acceptable provided they meet the required criteria for robustness.

- Consistent with achieving the specified performance, the ratio between external volume and vaccine storage capacity should be kept as low as possible. It is recommended that the ratio be kept to an absolute maximum of [22:1].
- The weight of coolant-packs must be the minimum needed to achieve the cold life required.
- Placement of coolant-packs must minimize temperature stratification within the load. However, if coolant-packs are located above the vaccine storage compartment they must not close off the vaccine storage compartment and prevent access during immunization sessions.
- Cooling of the container must be achieved using fully frozen ice-packs taken directly from a freezer room or freezer at -25°C. Integrated buffer materials and/or container configuration may be used to prevent freezing temperatures from propagating to the vaccine storage compartment. Water-based buffers as well as PCM-based buffers are allowed as of the published date of this document. If PCM is used, the material and design must comply with WHO/PQS/ E005/PCMC0.1– PCM specification for phase-change material containers..
- The design must eliminate the possibility of vaccine packages being exposed to air temperatures reaching 0°C, or contacting surfaces with a temperature of 0°C or less under any of the specified test conditions.
- The minimum possible number of user-interventions should be used to eliminate the possibility of vaccine packages or containers being exposed to freezing temperatures. The carrier design will be given a freeze protection classification based on the number of user-interventions. All pre-qualification testing must be carried out with a full complement of ice-packs, or warm water-packs. However, where such arrangements have the potential to extend the ambient operating temperature range of the product, manufacturers are free to describe alternative arrangements which comprise a mix of frozen and unfrozen coolant-packs of the same type. See clause 4.11.

4.2.7 Reuse cycle

It must be possible to reuse the container safely within 12 hours of removal of the previous charge of coolant-packs when the container is stored at the minimum rated ambient temperature.

4.2.8 Shape

The outside of the container may be any shape consistent with comfortable carrying. Rounded external corners are preferred. The vaccine storage compartment may be substantially square or rectangular, however, other shapes with horizontal, planar top and bottom are acceptable.

4.2.9 Lid

Vaccine carriers must be fitted with an insulated lid which fits securely to the body of the container when closed so as to minimize thermal bridging and maximize structural strength and resistance to transport vibrations and rough handling. Hinged lids are acceptable, but are not mandatory.

4.2.10 Hinges

Hinges, where fitted, must allow the lid to open beyond 90° to give full access to the interior of the vaccine carrier. Preferably the hinges should be recessed so that they are fully protected against damage during transport and storage. Hinges must be maintenance-free, without need for lubrication and must be

secured to the container in a manner which prevents loosening due to vibration.

4.2.11 Closure device

The lid should be fitted with a mechanism to secure it in place so that the vaccine carrier does not open if it is dropped onto its side or onto its lid when full. Acceptable closure devices include, but are not confined to, magnetic or mechanical catches. It must not be possible for a catch to open accidentally once engaged. Mechanical catches must be recessed so that they are fully protected against damage during transport and storage. Catches must be maintenance-free, without need for lubrication and must be secured to the container in a manner which prevents loosening due to vibration.

4.2.12 Carrying device

The body of the container must be fitted with one or more of the following carrying devices arranged so that the vaccine carrier can be comfortably carried in a substantially upright position:

- **Carrying handle:** A hinged, sliding or moulded-in handle, attached to, or forming an integral part of the container body or lid. When folded away, moveable handles must not extend beyond the maximum length, width or height of the container. The handle arrangement must not prevent stable stacking of the carriers.
- **Shoulder strap:** An adjustable strap arrangement which allows the vaccine carrier to be carried over the shoulder.
- **Backpack:** An adjustable padded strap arrangement which allows the vaccine carrier to be carried as a backpack.

All carrying devices must be robustly constructed and firmly attached in order to survive rough handling.

4.2.13 Primary container holding device

A holding device, if offered, should be designed to retain opened primary containers in a stable upright position during the course of an immunization session. The device must fully close off the vaccine storage compartment in order to limit air convection, limit loss of cold life, and keep the opened primary containers as cool as possible when the lid of the vaccine carrier is open. It must also be able to hold containers, with capacities ranging from one to fifty doses.

Design solutions may include, but are not limited to, the following:

- Soft foam plastic pad designed to receive primary containers. If indentations or slits are used, they must be designed so that containers are held from below and cannot be pushed through the pad.
- Moulded plastic tray with indentations to receive primary containers.
- Moulded plastic tray as previously described, but forming a separately hinged inner lid to the vaccine carrier.

Because of the risk of loss or damage, the holding device must be available to purchasers as a spare part if it is separate or easily removed from the carrier itself.

4.2.14 Vaccine storage advice

Vaccine carriers must have factory-fitted non-removable labels designed to last the lifetime of the container.

- **On the outside of the door or lid, and/or on the front face of the carrier: ‘**Stop!’ label as shown in Annex 1. These instructions should be predominately graphical.

- **On the inside of the door or lid:** Coolant and vaccine loading instructions and carrier preparation instructions as required as shown in Annex 2. This label must be in the UN language most appropriate to the country of use (Arabic, English, French, Mandarin Chinese, Russian or Spanish, or other language, by special order).

4.2.15 Stacking and handling

The design of the base and lid of the container should allow multiple units of the same model to be stacked on top of one another in a safe and stable manner. The base of the container must be designed to withstand repeated dragging across hard, rough floor surfaces.

4.2.16 Corrosion resistance

Hinges, stays, catches or handles and fixings, if metallic, must be constructed in stainless steel, aluminium, or suitable corrosion-resistant metal. Casings and linings, if metallic, must be constructed in stainless steel, aluminium, or using zinc coated steel sheet to EN 10152 with a corrosion-resistant plastics coating to EN 10169-1.

4.2.17 Chemical resistance

The external and internal surfaces of the container must be resistant to chemicals used for disinfecting (e.g. sodium hypochlorate, 5.25% in water).

4.2.18 IP rating

Protection of the container with lid closed and latched must not be less than IEC 60529: IP55.

4.2.19 Robustness and vibration

The container with a full coolant-pack load and a full load of vaccine vials and diluent ampoules must withstand a one metre drop onto each face, edge, corner, or chime (circumferential edge) when tested in accordance with ASTM D5276-09. At the end of the test there must be no damage that affects the performance of the carrier and the lid or door must still close and latch correctly. The container with a full coolant load and a full load of vaccine vials and diluent ampoules must withstand random vibration testing typical of unpaved road conditions in accordance with ASTM D4169-09, with no damage to either the container or contents.

4.2.20 Coolant-packs

The container must be provided with one full set of coolant-packs with complete installation and preparation instructions. Coolant-packs must comply with **PQS/E005/IP01**, Type 2 (0.3 litre), Type 3 (0.4 litre), or Type 4 (0.6 litre). Only one of these types may be used – a mix of the sizes is not acceptable.

4.3 *Environmental requirements*

4.3.1 Material properties at ambient temperatures:

Carrier materials must be able to withstand temperatures during transport, storage and use of -30°C to +70°C.

4.4 *Physical characteristics*

4.4.1 Overall dimensions

In conformity with clauses 4.5.1 to 4.5.3.

4.4.2 Weight

The maximum loaded weight of the container, inclusive of the recommended number of coolant-packs, must not exceed the following figures:

- **Short range:** 7.0 kg.
- **Long range**: 8.0 kg.

4.5 *Interface requirements*

4.5.1 Dimensional compatibility with coolant-packs

The dimensions of the coolant-pack locations must be compatible with coolant-packs complying with **PQS/E005/IP01** Type 2, 3, or 4. It is acceptable for the product to achieve its designated cold life at its designated vaccine storage capacity using only one of these types.

4.5.2 Dimensional compatibility with vaccine packaging

Vaccine carriers are generally used to transport mixed loads of vaccine in individual primary containers. The net dimensions of the storage compartment (length, breadth and height, with coolant-packs in place) should accommodate all types of pre-filled vaccine presentation and the complete range of standard vaccine vials and ampoules up to 50 dose size as well as tubes and pre-filled devices. Larger vaccine carriers may also be used to transport secondary cartons. The net dimensions of the storage compartment (length, breadth and height, with coolant-packs in place) should accommodate the widest possible range of routine vaccines supplied in these forms of packaging. Secondary cartons may be oriented in all three planes – for transport purposes it is not essential that vial caps face upwards.

4.5.3 Compatibility with distribution method

Containers must be designed so that they can be securely strapped, upright, to the luggage rack of a bicycle or light motorcycle.

4.6 *Human factors*

4.6.1 Generally

The product must be designed in accordance with the general usability principles laid out in ISO 20282-1.

4.6.2 Portability

Containers must be designed so that they can comfortably be carried, when fully loaded, for periods of several hours by a male or female health worker wearing traditional dress. Backpack units may be incompatible with some types of clothing.

4.7 *Materials*

4.7.1 Casing material selection

Internal and external casing materials must resist ultraviolet degradation caused by long-term exposure to sunlight. All joints or liners between the moulded components must be water and vapour proof, must be easy to clean and must be selected with environmentally safe end-of-life disposal in mind. Chlorinated plastics and composites containing epoxy, polyurethane, phenol formaldehyde and urea formaldehyde resins are not permitted.

4.7.2 Thermal *insulation foaming agents*

Any gas complying with the limitations and deadlines set by the Montreal Protocol on the elimination of ozone-depleting chemicals may be used. Insulation materials with a low global warming potential (GWP) are preferred. The chosen foam insulation material must be warrantied to have a Long-Term Thermal Resistance (LTTR) no worse than 7% lower than its rated ‘R’ value

at the time of foaming, when subjected to an accelerated ageing test in accordance with ASTM C1303 / C1303M-12.

4.7.3 PCM

Integrated thermal buffer materials may be used to prevent freezing temperatures from propagating to the vaccine storage compartment or for other thermal purposes. Water-based buffers as well as PCM-based buffers are allowed as of the published date of this document. If PCM is used, the material and design must comply with WHO/PQS/ E005/PCMC0.1– PCM specification for phase-change material containers.

4.7.4 Vacuum panels

Vacuum panel construction is an acceptable alternative to foam insulation provided the panels are warrantied to retain their vacuum for a minimum period of five years under the intended conditions of use.

4.8 *Warranty*

The product is to be covered by a two year replacement warranty in the event of any component failure arising from defective design, materials or workmanship. The manufacturer must state the time period over which the rated cold life is assured.

4.9 *Servicing provision*

The product is to be designed to achieve a maintenance-free life of not less than five years, apart from routine cleaning.

4.10 *Disposal and recycling*

The manufacturer is to provide information to the buyer on any hazardous materials contained within the product and suggestions for resource recovery/recycling and/or environmentally safe disposal.

4.11 *Instructions*

User and maintenance instructions must be provided in at least one of the UN languages Arabic, English, French, Mandarin Chinese, Russian, or Spanish, or other language by special order. If only one language is included it must be the language most appropriate to the country of use. The instructions need not repeat the information shown on the permanent labels, but must include guidance on how to repair minor damage.

4.12 *Training*

No requirement. Training on prevention of vaccine freeze damage and correct use of coolant-packs and warm-packs is the responsibility of the purchaser.

4.13 *Verification*

In accordance with PQS Verification Protocol **E004/VC02-VP.1**.

5. Packaging

Materials used for packaging the finished product are to be free of ozone-depleting compounds as defined in the Montreal Protocol. The general specification of shipping containers will be subject to agreement with the individual procurement agencies.

6. In-coming inspection

A random visual inspection of each batch of freeze-preventive vaccine carriers will be conducted by purchasing agencies. This inspection will generally be based upon **PQS/E004/VC02-VP.1** clause 5.2.1 (Test 1: Type examination), but may include other tests.

7. Product dossier

The legal manufacturer or reseller is to provide WHO with a pre-qualification dossier containing the following:

- Dossier examination fee in US dollars.
- General information about the legal manufacturer, including name and address.
- Unique identification reference for the product type.
- Brand name of the product.
- Full specifications of the product being offered, covering all the requirements set out in this document, including details of product marking and traceability.
- A set of digital photographs showing a three-quarter view of the unit with the entry closed, and three-quarter view with the door or lid fully opened and a top view of the interior with the full complement of coolant-packs in place.
- Certified photocopies of all type-approvals obtained for the product.
- Certified photocopies of the legal manufacturer's current ISO 9001 quality system certification.
- Where relevant, certified photocopies of the legal manufacturer's ISO 14001 certification, EMAS registration or registration with an equivalent environmental audit scheme. Conformity with an environmental audit scheme is not mandatory; however preference will be given to manufacturers who are able to demonstrate compliance with good environmental practice.
- Where available, laboratory test report(s) proving conformity with the product specifications.
- Indicative cost of the product per unit, per 10 units and per 100 units, including coolant-packs, EXW (Incoterms 2010).

8. On-site maintenance

The product is to be designed to be maintenance-free apart from repair of minor impact damage caused by dropping and the like. Consumable parts such as disposable insulation cover pieces are not permitted.

9. Change notification

The legal manufacturer or reseller must advise WHO in writing of any changes in form, fit or function which may affect the performance of the product after PQS pre-qualification has taken place.

10. Defect reporting

The legal manufacturer or reseller must advise WHO and the UN purchasing agencies in writing in the event of safety-related product recalls, component defects and other similar events.

Annex 1 – Label on outside of vaccine carrier

Notes:

1. Language: As required – see clause 4.11.
2. The label must be fixed to the outside of the door or lid or on the front face of the carrier.

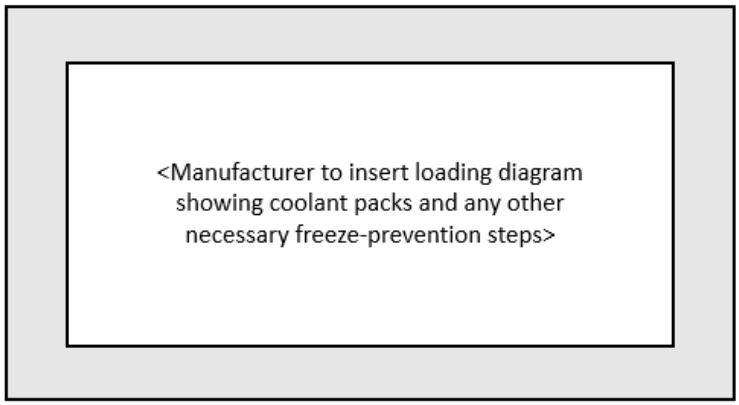
Annex 2 – Label on inside of lid

(Note: Label below is a generic format only)

Performance data:

+43°C cold life: <xx> hours with <xx> ice-packs.

ADDITIONAL DATA, IF REQUESTED BY THE PURCHASER
Cold climate freeze protection life: <xx> hours at -20°C with <xx> warm water-packs



Vaccine transport advice:

This container is designed to transport all vaccines with a labelled storage temperature of +2°C to +8°C.

DO NOT load vaccine into this container until you have checked that it is fully loaded with the correct coolant packs, prepared in accordance with the manufacturers instructions. DO NOT CONDITION ICE PACKS.

<The manufacturer must also include clear instructions for ensuring freeze-free performance as required>

ADDITIONAL DATA, IF REQUESTED BY THE PURCHASER
Use warm water-packs at +18°C for transporting freeze-sensitive vaccines in cold weather.

Manufacturer: <name> Model no: <ref> Date of manufacture/serial no: <xxxx>

Notes:

1. The layout of the label must suit the shape of lid in order to ensure maximum legibility.
2. Language: As required – see clause 4.11.
3. Optionally, the manufacturer's name, model number, dedicated GS-1 bar code with PQS prequalification number (e.g. PQS E00/xxx) and date of manufacture/serial number may be permanently fixed elsewhere on the container instead of inside the lid or door.

Annex 3 – Table of secondary carton sizes

Secondary cartons: This table shows secondary carton dimensions, weights and densities for 99 individual vaccine presentations procured by UNICEF (November 2011 data). The coloured blocks show that there are 16 carton groups that share identical dimensions. Maximum and minimum dimensions, weight and densities are shown at the bottom of the second column. The table is sorted by carton volume.

Vaccine	Width (cm)	Length (cm)	Height (cm)	Weight (grams)	Units per carton	Carton volume (cm^3)	Density (g/cm^3)
MMR	3.0	4.5	3.3	20	1	45	0.4
DTP+Hib	6.1	6.5	3.0	50	1	119	0.4
HepB	3.5	8.5	4.0	61	10	119	0.5
YF	5.5	15.0	1.5	42	10	124	0.3
YF	5.5	15.0	1.5	42	10	124	0.3
bOPV1+3	3.6	7.8	5.1	82	10	143	0.6
mOPV1	3.6	7.8	5.1	82	10	143	0.6
OPV	3.6	7.8	5.1	82	10	143	0.6
OPV	3.6	7.8	5.1	82	10	143	0.6
DTP+Hib	4.9	14.2	2.3	21	1	160	0.1
Hib_liq	4.2	8.8	4.4	73	10	163	0.4
HPV	4.1	8.7	4.7	0	10	168	0.0
YF	3.5	9.0	6.5	40	10	205	0.2
DTP-HepB	4.5	11.0	4.3	155	10	213	0.7
Measles	4.4	10.5	4.8	65	10	222	0.3
DTP	4.5	11.0	4.5	155	10	223	0.7
TT	4.5	11.0	4.5	150	10	223	0.7
DTP	4.7	10.6	5.1	184	10	254	0.7
Measles	4.7	10.6	5.1	126	10	254	0.5
MMR	4.7	10.6	5.1	126	10	254	0.5
MV A&C	4.7	10.6	5.1	126	10	254	0.5
YF	4.7	10.6	5.1	126	10	254	0.5
DTP-Hib	4.6	11.2	5.2	178	10	268	0.7
H1N1	4.6	11.2	5.2	178	10	268	0.7
HepB	5.0	11.5	4.8	230	10	276	0.8
YF	5.2	12.7	4.5	140	10	297	0.5
HepB	4.8	11.6	5.4	180	10	301	0.6
DT	5.5	12.5	5.5	200	10	378	0.5
Td	5.5	12.5	5.5	200	10	378	0.5
TT	5.5	12.5	5.5	256	10	378	0.7
Hib_lyo	8.5	14.7	3.3	110	10	412	0.3
MMR	8.5	14.7	3.3	110	10	412	0.3
bOPV1+3	11.0	11.0	3.5	390	25	424	0.9
BCG	10.1	15.2	3.0	82	20	461	0.2
DTP-HepB-Hib	8.5	17.0	3.6	315	50	520	0.6
HepB	11.0	11.0	4.3	246	36	520	0.5
bOPV1+3	11.5	11.6	4.0	380	25	534	0.7
mOPV1	11.6	11.5	4.0	460	25	534	0.9
mOPV3	11.6	11.5	4.0	460	25	534	0.9
OPV	11.6	11.5	4.0	460	25	534	0.9
bOPV1+3	8.5	17.0	3.8	415	50	549	0.8
mOPV3	8.5	17.0	3.8	415	50	549	0.8
OPV	8.5	17.0	3.8	415	50	549	0.8
HepB	10.5	14.0	4.0	254	35	588	0.4
DTP-HepB-Hib	8.5	17.0	4.5	36	50	650	0.1
HepB	8.5	17.0	4.5	34	50	650	0.1
HepB	8.5	17.0	4.5	37	50	650	0.1
BCG	8.0	16.7	5.0	390	50	668	0.6
PCV-13	9.2	17.9	4.1	360	50	675	0.5
HepB	11.1	13.0	5.0	33	20	722	0.0
HepB	10.6	14.1	5.3	330	35	792	0.4
Rota_liq	8.6	14.6	6.9	305	50	866	0.4
bOPV1+3	11.5	22.6	3.6	835	50	936	0.9
mOPV1	11.5	22.6	3.6	835	50	936	0.9
OPV	11.5	22.6	3.6	835	50	936	0.9
HepB	13.2	13.2	5.4	550	25	941	0.6
HepB	13.2	16.2	4.5	596	30	962	0.6
HPV	14.7	17.8	3.7	585	100	968	0.6
PCV-10	14.7	17.8	3.7	612	100	968	0.6
bOPV1+3	14.7	17.8	3.7	781	100	968	0.8
mOPV1	14.7	17.8	3.7	743	100	968	0.8
mOPV3	14.7	17.8	3.7	743	100	968	0.8
OPV	14.7	17.8	3.7	550	100	968	0.6
OPV	14.7	17.8	3.7	743	100	968	0.8
DTP-HepB	14.9	18.0	3.7	600	100	992	0.6
DTP-HepB+Hib	14.9	18.0	3.7	612	50	992	0.6
DTP-HepB-Hib	9.5	18.5	6.0	360	50	1055	0.3
DTP-HepB-Hib	9.5	18.5	6.0	737	50	1055	0.7
DTP-HepB+Hib	9.5	18.5	6.0	406	50	1055	0.4
Measles	9.5	18.5	6.0	403	50	1055	0.4
Measles	9.5	18.5	6.0	410	50	1055	0.4
MR	9.5	18.5	6.0	405	50	1055	0.4
MMR	9.5	18.5	6.0	405	50	1055	0.4
MMR	9.5	18.5	6.0	405	50	1055	0.4
MMR	9.5	18.5	6.0	405	50	1055	0.4
Men A	9.5	18.5	6.0	405	50	1055	0.4
BCG	9.5	18.5	6.0	374	50	1055	0.4
DT	9.5	18.5	6.0	737	50	1055	0.7
TT	9.5	18.5	6.0	737	50	1055	0.7
Td	9.5	18.5	6.0	737	50	1055	0.7
DTP	9.5	18.5	6.0	740	50	1055	0.7
HepB	9.5	18.5	6.0	268	50	1055	0.3
HepB	9.5	18.5	6.0	737	50	1055	0.7
DTP-HepB	9.5	18.5	6.0	737	50	1055	0.7
TT	13.3	13.3	6.0	707	25	1061	0.7
DTP	13.3	13.3	6.0	707	25	1061	0.7
MV ACWY	10.8	25.3	4.2	700	50	1148	0.6
TT	12.0	15.0	6.5	551	20	1170	0.5
Rota_liq	8.4	13.0	11.1	no data	25	1220	no data
HepB	14.0	17.0	5.5	610	30	1309	0.5
TT	14.0	17.0	5.5	610	30	1309	0.5
mOPV1	12.7	14.8	7.5	580	100	1410	0.4
mOPV3	12.7	14.8	7.5	580	100	1410	0.4
OPV	12.7	14.8	7.5	461	100	1410	0.3
OPV	12.7	14.8	7.5	580	100	1410	0.4
BCG	13.3	13.6	8.0	51	100	1447	no data
DTP-HepB	10.8	25.3	5.5	950	50	1503	0.6
MR	10.0	19.5	10.0	840	100	1950	0.4
TT	15.4	16.8	12.0	303	100	3105	0.1

Minimum:	**3.0**	**4.5**	**1.5**	**0.1**	**1**	**45**	**0.0**
Maximum:	**15.4**	**25.3**	**12.0**	**950.0**	**100**	**792**	**0.9**

Revision history:			
Date	Change summary	Reason for change	Approved
27/08/2018	Section 4.2.6 edited	Reflect change to allowance of water-based and PCM-based buffers and added reference to new PCM draft specification	*Revised by: Steve DeSandis* *Approved by: Isaac Gobina*
27/08/2018	Section 4.7.3 edited	Reflect change to allowance of water-based and PCM-based buffers and added reference to new PCM draft specification	*Revised by: Steve DeSandis* *Approved by: Isaac Gobina*