

## **Annex 6. Technical Requirements for Packing, Packaging and Labelling**

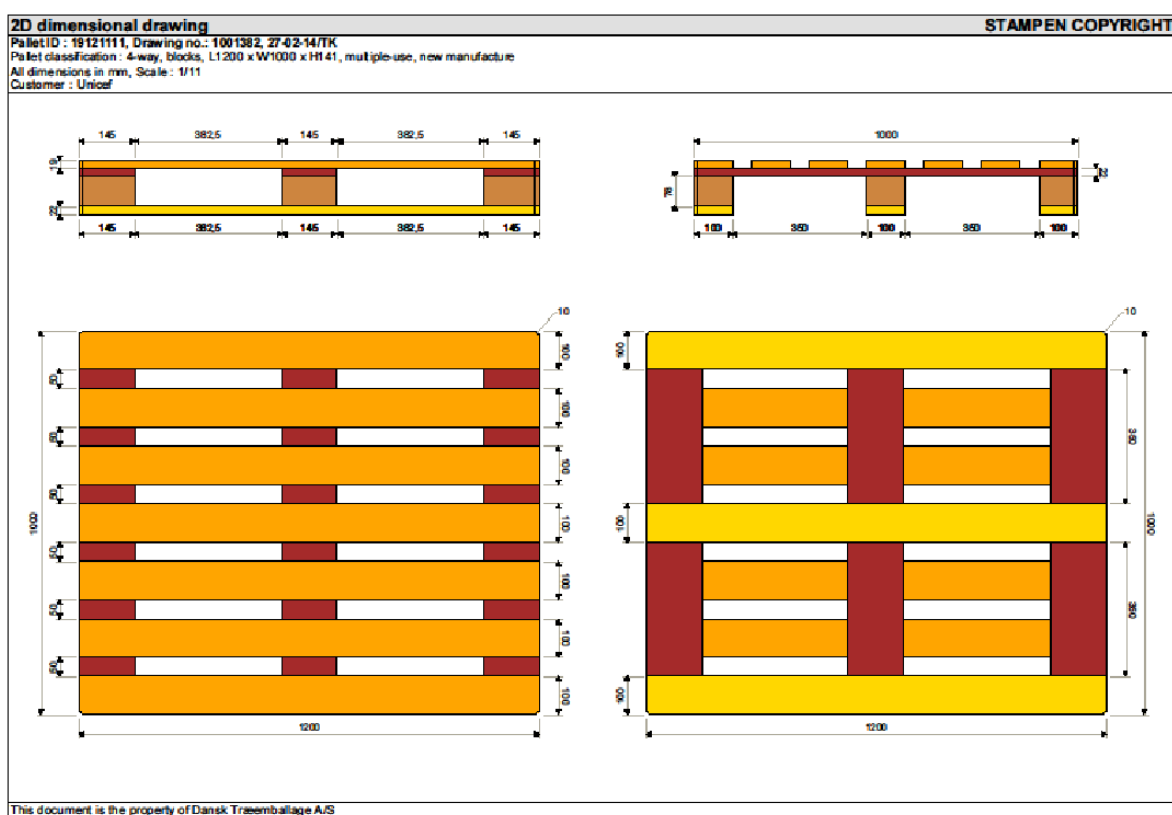
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## 1. General Requirements

- 1.1 The below requirements on palletization, packaging and labelling apply to **all shipments**.
- 1.2 For non-compliant shipments, UNFPA reserves the right to reject them. All additional costs in relation to the rejection of the shipment shall be borne by the awarded BPA supplier.

## 2. Pallets

### 2.1 Pallet size



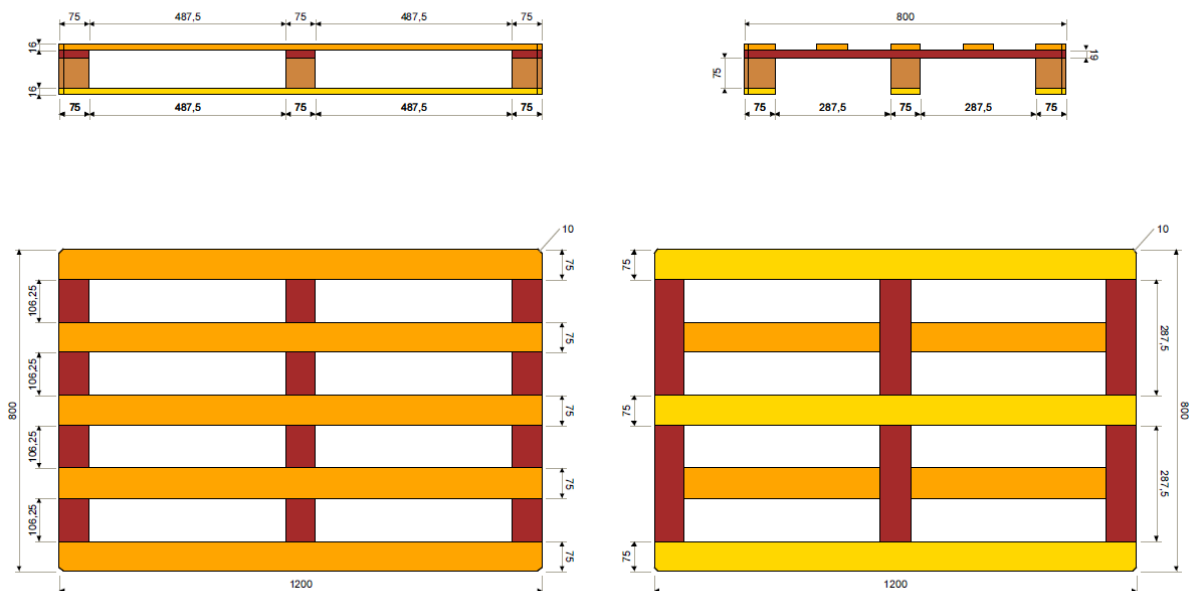
2.1.1 1200 x 1000 mm (Preferred size), One Way Pallet, Heat treatment according to ISPM 15

Nails/Joint:	Deck board/Block	2 pcs. 3.1/85 mm ring nail
	Deck board/Stringer board	2 pcs. 2.5/45 mm round nail (diamond shaped)
	Bottom board/Block	2 pcs. 3.1/75 mm ring nail

Tolerances:	Pallet length	-0/+3 mm
	Pallet width	-0/+3 mm
	Board length	-0/+3 mm

	Board width	-3/+3 mm
	Board thickness	-0/+1 mm
	Block length	-3/+3 mm
	Block width	-3/+3 mm
	Block height	-0/+2 mm
	Entry height	Min. 100 mm
Wood:	Moisture content	<20 %
	Wanes	<15 mm
	Single knot	<1/3 of width
	Sum of knots	<1/2 of width
	Insect holes and rot are NOT allowed	
	Heat treatment According to ISPM 15	

### 2.1.2 1200 x 800 mm, One Way Pallet (Euro) as per UIC 435-2 , Heat treatment according to ISPM 15



Nails/Joint:  shaped)	Deck board/Block	2 pcs. 3.1/85 mm ring nail
	Deck board/Stringer board	2 pcs. 2.5/45 mm round nail (diamond
	Bottom board/Block	2 pcs. 3.1/75 mm ring nail

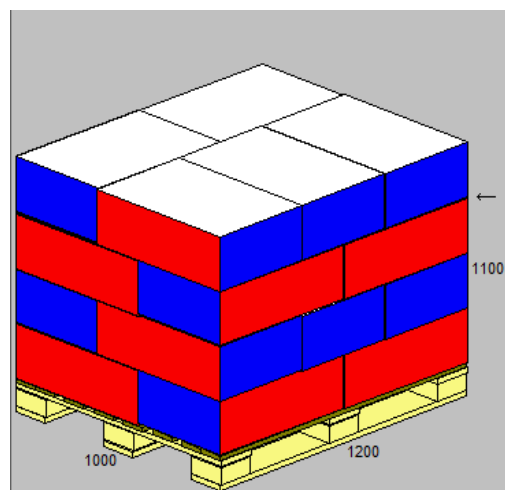
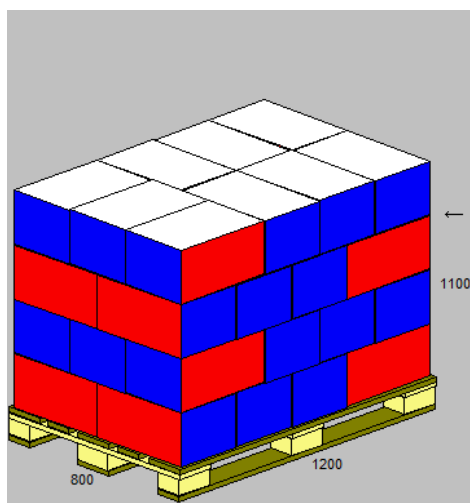
Tolerances:	Pallet length	-0/+3 mm
	Pallet width	-0/+3 mm
	Board length	-0/+3 mm
	Board width	-3/+3 mm
	Board thickness	-0/+1 mm
	Block length	-3/+3 mm
	Block width	-3/+3 mm
Block height		-0/+2 mm
	Entry height	Min. 97 mm
Wood:	Moisture content	<20 %
	Wanes	<15 mm
	Single knot	<1/3 of width
	Sum of knots	<1/2 of width
	Insect holes and rot are NOT allowed	
	Heat treatment According to ISPM 15	

## 2.2 Carton stacking

The height of the pallet will depend on the selected mode of transport. For air freight, usually, the height must be not higher than 150-160 cm, but this may vary depending on the type of aircraft. In the case of IARH kits, the palletization should follow EU standards with dimensions 120x80x140cm, to achieve better storage and space utilization, which is also required by the warehouse where UNFPA keeps stocks.

The maximum weight of the cargo, including the pallet, is usually **950 kg**. However, depending on the situation and capacity utilization with regard to containerization, weight and height could be adjusted after the Country Office's (consignee's) approval.

The cartons shall be cross-stacked on the pallets whenever possible (as per the example given below). No overhang is allowed. The cargo on the pallets shall be shrink-wrapped. The shrink-wrapping shall allow the pallet to be handled by fork-lift. Loose foil ends are not tolerated. Pallets must not be wrapped together.



### 2.3 Cargo

The pallets/cartons shall contain **only** one material.

For batch managed materials, e.g. pharmaceuticals and medical devices, the cartons/pallets shall contain **only** 1 single batch.

### 2.4 Wrapping

The cargo on the pallets shall be shrink-wrapped.

The shrink-wrapping shall allow the pallet to be handled by fork-lift.

Loose foil ends are not tolerated.

Pallets must not be wrapped together.

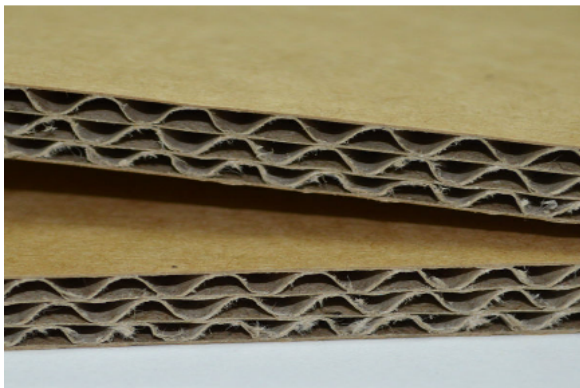
### 2.5 Strapping

As an alternative to shrink-wrapping, the cargo can be fixed with straps of polypropylene. Steel straps are not acceptable.

The cargo shall be fixed with at least 4 straps, 2 on the pallet's short side and 2 on its long side.

## 3. Packaging requirements

The packing of the product(s) shall be suitably over-packed for shipment in strong triple-wall cardboard boxes (picture is provided below) and in a manner that shall provide adequate protection of the goods with sufficient buffering of the equipment for carriage by air, sea, and road to final destination and subsequent in-land distribution including remote locations under adverse climatic and storage conditions, and high humidity – i.e. not less than 17kN edge crush resistance with minimum 60% remaining with 90% at a temperature of 40°C (tropical conditions).



Outer cartons shall be numbered consecutively. No carton may contain items from more than one manufacturing batch. Cartons containing non-uniform contents must be specially marked with red at the top corners.

Case identification as requested on the order must be mentioned on all invoices.

Packaging of product shall comply with WHO GMP standards:

- Primary packaging – sterile or non-sterile as appropriate. E.g. for sterile items, transparent film to allow clear identification of the content – sachet, plastic box, peel-off sachet. For

pharmaceutical products with 30 tablets/capsules or less, it shall be in blister pack. For item with more than 30 tablets/capsules, it should be in bottle;

- Secondary packaging – to protect the primary packaging – e.g. cardboard, rigid wrapping.

#### Marking and labelling for pharmaceutical products

The labelling of the product shall meet the following requirement:

a. Primary packaging shall be imprinted with the following:

- Name of manufacturer
- Address of manufacturer's manufacturing site – where there is space enough
- Article reference of the manufacturer and the supplier
- Details to identify device in English, French and Spanish; description, composition as appropriate
- Batch number prefixed by the word "LOT" or equivalent harmonised symbol
- Items with limited shelf life, expiry date using the words "use before (month)/(year) or prefixed by "EXP" or equivalent harmonised symbol (month)/(year)
- Items without expiry date, the date of manufacture (year) prefixed by the harmonised symbol, unless information already incorporated into the batch number or serial number
- For single use items, the words "DO NOT RE-USE" or "FOR SINGLE USE" or equivalent harmonised symbol
- For sterile items, the word "STERILE" or equivalent harmonised symbol, plus a warning which advises to "check the integrity of the sterile packaging before use."
- Name of drug;
- Pharmaceutical dosage form
- Active pharmaceutical ingredient(s); type and amount;
- Net quantity per unit
- Instructions/direction for use
- Storage conditions including warnings and precautions
- If reconstitution is required, state the storage conditions after reconstitution and shelf-life;

a. Secondary packaging for pharmaceutical products shall be imprinted with the following:

- Name of manufacturer
- Address of manufacturing site
- Labelling same as on primary packaging, in addition –
- Any special storage conditions and or handling conditions
- Instructions for use in English, French and Spanish.
- [WHO Guidelines on packaging for pharmaceutical products, Annex 9, TRS 902, 2002](#)

a. Summary of Product Characteristics, package inserts and Patient information leaflets. The content should be in line with WHO SPC template which may be accessed at [ANNOTATED SUMMARY OF PRODUCT \(SmPC\) CHARACTERISTICS TEMPLATE](#)

#### Marking and labelling for Medical Devices products

Primary packaging shall be by unit of use and secondary packaging shall provide protection of the packaged individual units in a box.

Labelling shall meet, at least, the requirements described in the Global Harmonization Task Force document: GHTF/SG1/N70:2011: Label and instruction for Use for Medical Devices. The language should be in English or Spanish or French as specified.

Symbols used with medical device labels, labelling and information to be supplied (e.g. Information For Use leaflet) shall comply with the current version of ISO 15223 Part 1.

Labelling on the medical device itself (if on medical device itself it should be in a format that will not be dislodged during cleaning, disinfecting or sterilization of the device) or on the primary packaging of each unit or on the primary packaging of multiple devices should contain the following where applicable:

- Name and/or trademark of the manufacturer including the full address of the manufacturer. *Name and address of Authorised Representative or Distributor may be added but this additional label should not obscure any of the manufacturer's labels.*
- Manufacturer's product name with additional reference number or product code
- UDI code in accordance with the EU Council Directive 93/42/EEC (MDD) or EU Regulations 2017/745 (MDR).
- Type of product and main characteristics, i.e. details to identify the device and its use.
- If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging.
- Lot number prefixed by the word "LOT" (or equivalent harmonised symbol, if applicable)/batch code or serial number. Manufacture date should be additionally indicated.
- For products supplied sterile or for single use disposable devices, the label should clearly state STERILE and/or DISPOSABLE or SINGLE USE (or equivalent harmonised symbols). Additionally, a date of expiry is to be stated with clear indication to expiry year and month before which the device is considered to be safe to use. In order to verify the stated shelf life, the date of manufacture must be included in the label. Labels should include the used sterilization method where applicable.
- Information for particular storage conditions that apply (temperature, pressure, light, humidity, etc., as appropriate must be read in the package (or equivalent harmonised symbols).
- Information for handling (e.g. warnings) or instructions for use, if applicable (or equivalent harmonised symbols).

For devices that have CE marking approval, the CE mark should be on the item itself, or on the primary packaging as appropriate. Please note: if on device itself, this should not be removable during handling, use or cleaning of the device.

## 4. Cartons

### 4.1 Export cartons

#### 4.1.1 Design

Box style	Full-overlap slotted container (FOSC)
FEFCE/ESBO Code	0203 modified as described below
Closure	Outside flap, glued and stitched
Flute designation	BC triple wall (7 layers)
Structural instructions	Meeting inner flaps. All corners of long side flaps are chamfered 25x25 mm.

#### 4.1.2 Quality and standards

Edge Compression Test (ECT)	$\geq 17 \text{ kN/m}$	(EN ISO 3037)
Bursting strength (Mullen)	$\geq 2200 \text{ kPa}$	(EN ISO 2759)
Water absorptiveness (Cobb 1800)	$< 155 \text{ g/m}^2$	(EN ISO 535)
Bending stiffness	MD: $\geq 44000 \text{ Nmm}$ CD: $\geq 19500 \text{ Nmm}$	(EN ISO 5628)

#### Quality instructions

Min. 60% of resulting box strength must be maintained in tropical conditions, i.e. 40°C and 90 % R.H.

Box compression test (BCT) must be provided.

### 4.2 Inner cartons

#### 4.2.1 Design

Box style	Regular slotted container (RSC)
FEFCE/ESBO Code	0201 modified as described below
Closure	Inside flap, glued
Flute designation	C single wall
Structural instructions	All corners of short side flaps (inner flaps) are chamfered 10 x 20 mm (10 mm on top edge).

#### 4.2.2 Quality and standards

Edge Compression Test (ECT)	$\geq 6,1 \text{ kN/m}$	(EN ISO 3037)
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Bursting strength (Mullen)	≥ 1680 kPa	(EN ISO 27597)
Water absorptiveness (Cobb 1800)	< 155 g/m <sup>2</sup>	(EN ISO 535)
Bending stiffness	MD: N/A, CD: N/A	(EN ISO 5628)

#### 4.2.3 Quality instructions


Min. 60% of resulting box strength must be maintained in tropical conditions, i.e. 40°C and 90 % R.H.

Box compression test (BCT) must be provided.

## 5. Labelling

Labelling is required for tertiary packaging (export cartons) and pallets.

The label shall contain UNFPA's order number, UNFPA's item/kit ID and description as well as the quantity of the packaging. For batch-managed materials, batch number, manufacture and expiry dates are also required. The marking and labelling on export cartons shall strictly adhere to the following UNFPA requirements:

 <p><i>UNFPA/Project No.:</i> <i>Contents:</i> <i>Country of destination:</i> <i>UNFPA PO No.:</i></p>	<ul style="list-style-type: none"> <li>• Supplier name</li> <li>• Lot/Batch/Serial numbers</li> <li>• Case / Carton number</li> <li>• Manufacturing date</li> <li>• Expiry date for appropriate items</li> <li>• Weight</li> <li>• Volume</li> <li>• Max. temperature, if applicable</li> <li>• Specific instructions (if any)</li> </ul>
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If special storage, transport and/or handling conditions are required, labelling indicating such requirements shall also be affixed visibly both to the tertiary packaging and the pallet. For temperature-sensitive goods, both the tertiary packaging and the pallets shall be clearly and visibly labelled with the storage and transport temperature requirements. For goods classified as dangerous goods, both the tertiary packaging and the pallets shall be clearly and visibly labelled with the storage and transport requirements.

All the requested labelling information should be ink printed in the tertiary packaging and not be added through stickers or any other form, where there is a risk of removal or loss.

All tertiary packaging (cartons) shall be numbered consecutively.

### 5.1 Date formats

Only the below Manufacture/expiry date format should be used:

YYMMDD

## **5.2 Label positioning**

The labels shall be affixed to the two short sides of the pallets, outside the plastic wrapping.

## **6. Packing List**

### **6.1 Single shipment**

A detailed packing list shall be attached to both short sides of minimum the first pallet of the shipment, including UNFPA's Order number, UNFPA's item/kit ID and description, quantity and manufacturing batch number/s if applicable, expiry date if applicable, gross weight, dimensions and cross-reference to the carton numbers and markings including the full consignee address. The packing list must contain the same UoM (unit of measure) as indicated in UNFPA's Order. The markings on the boxes shall be as per UNFPA's Order instructions.

### **6.2 Multiple shipments**

In case of multiple shipments of the same order, separate/individual packing lists must be prepared for each container/truck to ensure smooth and correct goods' receipt.

UNFPA reserves the right to request changes in the marking and labelling to be printed on shipping cartons.