

# **Spare Parts Standards**

## *Inbound Logistic Guidelines - Spare Parts*

<b>1</b>	<b>Objective</b> .....	<b>2</b>
<b>2</b>	<b>Ground Rules</b> .....	<b>2</b>
<b>3</b>	<b>Document Requirement for receiving</b> .....	<b>3</b>
<b>4</b>	<b>Packaging</b> .....	<b>6</b>
<b>5</b>	<b>Labelling</b> .....	<b>11</b>
<b>6</b>	<b>Repaired Spare Parts / Material Reworks</b> .....	<b>14</b>
<b>7</b>	<b>Batch Management</b> .....	<b>14</b>
<b>8</b>	<b>Delivery Address</b> .....	<b>14</b>
<b>9</b>	<b>Glossary</b> .....	<b>14</b>

## 1 Objective

The purpose of this document is to establish supplier requirements and guidelines for shipments to RDG's Distribution Center Spare Parts (Mannheim, Germany) and to achieve optimum quality deliveries that are free of damage, have proper part identification and labeling consistency. All Suppliers must comply with all government regulations pertaining to the importation of goods and comply with additional Roche requirements concerning invoicing, transportation, packaging, labeling and security.

## 2 Ground Rules

- 2.1 Spare parts shall be individually packed for safe storage and shipment. The supplier shall be responsible for selecting a satisfactory quality of packaging material and an adequate packaging design. This has to be adapted to the anticipated means of shipping, storage, and transportation as well as environmental influences (sufficient protection against damage and soiling).
- 2.2 The choice of the packing type and the requirement of particular protections depend on characteristics of the equipment and material to be packed, its handling requirements and kind of transport chosen. Size of packaging shall be adequate and in correlation to the size of the Spare Parts to minimize the amount of materials used while maintaining adequate protection for the spare part itself.
- 2.3 The quantity of parts contained in each unit package shall be one (1) or an appropriate quantity which is used for a single service case. For low cost parts an optimized economic packaging quantity should be defined during setup of a new spare part by the Supplier.
- 2.4 Spare parts packaging shall be uniquely labeled and sealed according to Roche standards to ensure efficient and handling within the Supply Chain Spare Parts.
- 2.5 Spare Parts with specific environmental conditions for storage and shipment shall be avoided. Dangerous Goods Shipments, Temperature controlled shipment with temperature logger and Temperature sensitive products with validated shipping methods (< -70° Celsius) are not possible in the Supply Chain Spare Parts.
- 2.6 Spare Parts, packaging, packaging material shall be in compliance with the current effective environmental regulation to avoid limitations and penalties in worldwide distribution.
- 2.7 Deviations from these Inbound Logistic Guidelines and changes in packaging specifications, packaging sizes, packaging content and labeling will only be accepted prior to written approval by RDG.

### 3 Document Requirement for receiving

#### 3.1 General Requirements:

- All documents must be in English or in German (for German suppliers only).
- Commercial invoice currency must match the RDG purchase order and billing currencies.
- For air and truck shipments, provide the commercial invoice and the Air Waybill/Bill of Lading to the party who will be transporting your goods.

#### 3.2 Commercial Invoice Requirements

- The commercial invoice must accompany all shipments delivered to DCS Mannheim, and must match the billing (or "no charge") invoice. EXCEPTION: A commercial invoice is NOT required for intra-EU (European Union) shipments.
- Information on the commercial invoice must match exactly the physical goods being shipped and must be consistent with all related documentation (e.g. air waybill / bill of lading, packing list, etc...) and shipping labels.
- Unless there are additional "no charge" items listed on the commercial invoice which are not billable, the commercial invoice sent with the shipment must be the same as the billing invoice sent to Roche for payment. If any items are provided free of charge ("no charge") they must have accurate values assigned to them for Customs declaration purposes. The statement "Value for Customs - Purposes Only" must be included in the invoice.
- Shipments to Roche should be made using Roche's contracted carriers, unless otherwise specified. The contracted carrier may vary depending on the departure location and destination of your shipment.
- Your Procurement Representative will provide specific information on the purchase order (PO) that must be included on the commercial invoice (e.g., Roche material numbers, Descriptions etc...). One original plus two copies of the commercial invoice must accompany shipments to most countries.

#### **The following data elements are required on the commercial invoice**

- a.) The commercial invoice number.
- b.) Invoice date.
- c.) Sold To and Ship To complete address. The invoice must indicate that the "bill to", "invoice to" or "sold to" company is RDG, not just "ship to RDG. This information is required so it is clear that RDG is able to act as importer of record for the shipment.
- d.) Shipped From: Supplier complete address, including a contact name and phone number.
- e.) The delivery terms (Incoterms) for the shipment.
- f.) Quantity of cases.
- g.) Weights; total gross and net metric weight (kilograms) of each individual case in the shipment must be shown separately.
- h.) Dimensions; total metric (centimeters) length, width and height of each individual case in the shipment must be shown separately.
- i.) The description of the product being shipped. The invoice description must be clear, precise, and

sufficient for Customs in the importing country to verify the identity of, and classification of, the items listed on the commercial invoice and contained in the import shipment. Use of acronyms, abbreviations, and industry specific terms should be avoided.

j.) The RDG Purchase Order (PO) number.

k.) The name of the RDG Procurement Representative

l.) The Roche material number (or machine type and serial number). If there is no Roche Material Number assigned, the supplier part number should be provided. Use supplier part number only if no Roche material number has been assigned.

m.) Country of Origin - required for each line item

**The commercial invoice must provide country of origin information using:**

The 2-character ISO code and the full name of the country, in English; or

The 2-character ISO code (e.g., US, FR, TW); or The full name of the country in English.

In all instances, the country of origin information on the invoice must be consistent with the country of origin marked on the immediate container and the article and consistent with the country of origin identified on the packing list (delivery notice).

n.) Unit of Measure from the Harmonized Tariff System (e.g. PCS, PK , KG, CM, ML)

o.) Quantity of product shipped.

p.) Invoice currency must match purchase order and billing currencies. Euro (EUR) is preferred, local currency is acceptable, if convertible.

q.) Unit Price; the unit price of each item shipped.

r.) Amount; the Extended Total Price of each item (i.e. quantity x unit price).

Note: Unit Price and Extended Total Price must be consistent with the RDG PO and the billing invoice submitted to RDG for payment. If the shipment does not represent a shipment against a PO, and the parts are shipped at “no charge” (no payment expected), a fair market value should be referenced.

s.) Total Value of Goods; the sum of all the line item total prices for the invoice.

t.) Any additional charges associated with the shipment. “Additional Charges” on the invoice may include charges for international freight, special handling, expedited delivery, commissions, and similar items. These charges must be listed on your PO for payment to be made.

u.) Invoice Total; the total value of all items and related additional charges. Identify this amount with the statement “Total Invoice Amount Payable”.

### 3.3 Packing List Requirements

Suppliers are required to provide one (1) copy of the packing list which must be placed in an envelope attached to each separate case. If the goods are palletized, only one (1) copy is needed for each pallet. Alternately, the packing list may be sealed inside the case, with the words "Packing List Enclosed" placed on the outside of the package. The packing list may contain all information shown on the commercial invoice, with the exception of all pricing related information which must be removed.

The packing list must include the following information at a minimum:

- Name of Supplier
- RDG Purchase Order (PO) number (if applicable)
- Roche material number (s)
- Quantity of each part number
- Country of Origin for each part number
- Lot, Batch or Serial Number (if applicable) and Quantity per lot
- Expiration Date (where applicable)
- Storage and Temperature Conditions (where applicable)
- Case / Colis / Carton Box Number

A copy of the commercial invoice (after pricing information has been removed or obscured) may be used as the packing list. The packing list (delivery notice) must provide the country of origin information using the full English name of the country, the 2 character ISO code, or an appropriate abbreviation for the country. In all instances, the country of origin information on the packing list (delivery notice) must be consistent with the country of origin marked on the immediate container, article and commercial invoice.

### 3.4 Air Waybill

An air waybill (AWB) must accompany each air shipment. A minimum of one original plus three additional copies are required. The following information must be included on the AWB; three additional copies are required.

The following information must be included on the AWB:

- Shipper Information (Name, Address, Account #).
- Consignee Name & Address (must be consistent with destination "ship to" address as per commercial invoice and purchase order).
- The commercial invoice numbers for all goods in the shipment.
- Goods Value (note: declared values for Carriage or Insurance must be "NVD" (No Value Declared)).
- Number of Pieces (Cases, Pallets, etc...).
- Reference Numbers (Case, Pallet Numbers, etc...).
- Weights & Dimensions (metric unless English system specifically requested).
- Description of Goods.

- Special Shipping Instructions (if applicable).
- Utilize the normal IATA AWB form provided by the carrier and complete all required fields.

Information on the air waybill must be consistent with all related documentation (e.g. invoice, packing list, etc...) and shipping labels.

### 3.5 **Sea Waybill, Ocean Waybill and Truck Bill of Lading (BOL)**

A bill of lading (BOL) must accompany each truck or ocean shipment. A minimum of one original plus three additional copies are required.

The following information must be included on the bill of lading:

- Shipper Information (Name, Address, Account #).
- Consignee Name & Address (must be consistent with destination "ship to" address as per commercial invoice and purchase order).
- Date when material was shipped
- The commercial invoice numbers for all goods in the shipment.
- Goods Value (note: declared values for Carriage or Insurance must be "NVD" (No Value Declared)).
- Number of Pieces (Cases, Pallets, etc...).
- Reference Numbers (Case, Pallet Numbers, etc...).
- Weights & Dimensions (metric unless English system specifically requested).
- Description of Goods.
- Special Shipping Instructions, like Temperature conditions (if applicable).

Information on the Bill of Lading must be consistent with all related documentation (e.g. invoice, packing list, etc...) and shipping labels.

## 4 **Packaging**

The selection of the packaging depends primarily on its economic efficiency as well as its environmental compatibility. Recommended standard packaging is disposable or reusable packaging. Its use, however, depends on the delivery volume, the distance, and, thus, its economic efficiency. The supplier shall be responsible for selecting a satisfactory quality of packaging material and an adequate packaging design. This has to be adapted to the anticipated means of shipping, storage, and transportation as well as environmental influences (sufficient protection against damage and soiling).

Within the start of the product life cycle the development of the packaging can be undertaken by the supplier, in case this has an advantage due to process know-how and product know-how of the Supplier. The responsible RDG packaging planner and Supplier finally agree on the product-specific

packaging (packaging instruction) which is binding for future shipments. Any changes in packaging specifications, packaging sizes, packaging content will only be accepted prior to written approval by RDG.

**The following basic principles must be followed:**

- Avoidance of packaging (as much as possible).
- The packaging must not be larger or more elaborate than essential to protect the goods.
- Padding material should be kept to a minimum.
- Where disposable and returnable packaging is used, recyclable packing materials must be used and identified according to the specifications of the waste management industry.
- Use of single-type component materials. Composite Materials are not allowed.
- Where disposable and returnable packaging is equal in economic and qualitative terms, returnable packaging shall be preferred.
- Returnable packaging (e.g. Euro pallets, Euro box pallets, small load carriers) that is capable of pooling (used through multiple processes and partners) is to be preferred ahead of returnable packaging without such capability.
- Returnable packaging should correspond to standard sizes.
- Special design and sizes should only be defined as exception in case of specific/ extraordinary requirements of the material to be delivered.
- Returnable packaging must be designed to be cleaned, emptied and drained easily.

**4.1 Minimum requirements for packaging of spare parts:**

- Single packaging of spare parts (preferred)
- Impact resistant and Break-proof (to prevent transport damages)
- Size of packaging adequate in relationship between size of spare part and safety
- Original packing banderole or security seal on the chamfer of the packaging
- Electronical parts should be packed in anti-static foil additionally
- For moisture-sensitive components use “dry pack”
- If necessary, labeling with pictograms according to DIN EN ISO 780 and/or Dangerous Goods Ordinance (please note: Dangerous Goods can normally not transported in Supply Chain Spare Parts)

**4.2 Corrugated Containers**

Generally, the selection of a corrugated container will depend on the specific component, method of transportation and the method of handling by both the supplier and receiver.

- Roche prefers and highly encourages the use of recycled materials.
- Other factors to consider are:
  - Handling Labor
  - Handling equipment
  - Transportation cost
  - Packaging
  - Direct Labor
- When volumes warrant, palletizing is required.
- Individual containers should not weigh greater than 28 kg or 60 pounds.
- All containers, trays and lids must have a manufacturer's certificates with bursting, puncture or ECT (edge crush test) limits visible on the underside (bottom) of the assembled container.
- Rice Paper or yellow corrugated is not allowed.

**Containment:**

The only acceptable methods of sealing manually handled cartons are strippable reinforced, asphaltic, or plastic tapes, and spot gluing. Staples are only acceptable with prior approval from the Roche Receiving Department.

- All cartons must be secured to a pallet.
- The preferred method of securing material(s) to pallets is plastic, heat sealed strapping of polyester, shrink/stretch film (PVC films are unacceptable) and unitizing adhesives for cartons.
- When shrink /stretch films are used, labels used and adhered to the film are encouraged to be of the same material as the film for ease of recycling.
- Metal banding is only acceptable when prior approval is obtained.

**4.3 Packing Materials**

The preferred packing material for partial container(s) is Bubble Pack/Air Pillows. Paper can also be used for packing material.

The use of Styrofoam packing peanuts is not acceptable Packing Material for Roche Shipments.

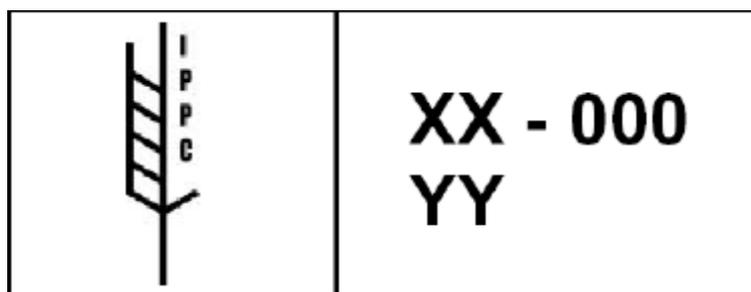
All shipments, regardless of origin or destination, with packaging components made of non-manufactured wood packaging (NMWP), (e.g., skids, pallets, crates, dunnage) must meet the minimum requirements listed below. These requirements are derived from regulations typically being adopted in many countries and globally harmonized standard (ref. ISPM 15, updated in 2009): <https://www.ippc.int/id/13399>

ISPM: International Standard for Phytosanitary Measures

IPPC: International Plant Protection Convention

In summary, all non-manufactured wooden packing materials (NMWP) regardless of origin, destination or species (e.g., dimensional lumber) shall be debarked, treated and marked per ISPM-15.

All NMWP (regardless of wood species) must undergo heat treatment to achieve a minimum wood core temperature of 56 degrees centigrade (133 degrees F) for a minimum 30 minutes. Additionally, NMWP must then be marked a minimum of two times with the IPPC logo and treatment initials per sample below.



XX = 2 character abbreviation of the Country Name where treatment occurred  
 000 = 3 digit treatment facility code provided by the Nat'l. Plant Protection Org.  
 YY = 2 character abbreviation of the Treatment Type (HT = Heat Treated)

Although manufactured wood (e.g., plywood, OSB, presswood, masonite, etc...) is not subject to these restrictions, Roche still require these be marked to distinguish them from the restricted non-manufactured type wood. There is no officially sanctioned marking for composite / manufactured wood.

#### **Restrictions on Dimethyl Fumarate (DMF) in products or packaging.**

In an attempt to restrict/eliminate the use of the skin irritant dimethyl fumarate (DMF), the European Union issued Commission Decision 2009/251/EC .  
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:074:0032:0034:EN:PDF>

DMF may be present in some types of desiccants (silica gel) used during shipment. Products or packaging containing DMF are not approved for import into the EU. Roche has taken actions to ensure that all desiccants used for Roche spare parts and products are compliant with the EU restrictions on DMF.

#### **4.4 Pallet Guidelines**

- Expendable pallets are designed specifically for one-trip only.
- Four-way entry pallets are designed to permit entry of fork or pallet jacks from all sides.
- Notched stringer is designed to permit four way entry for forklift and two entry for pallet jacks.
- Deck boards make up the faces of a pallet and either carry or rest upon the goods packed.
- Stringers are the wooden runners to which the deck boards are fastened and serve as a spacer

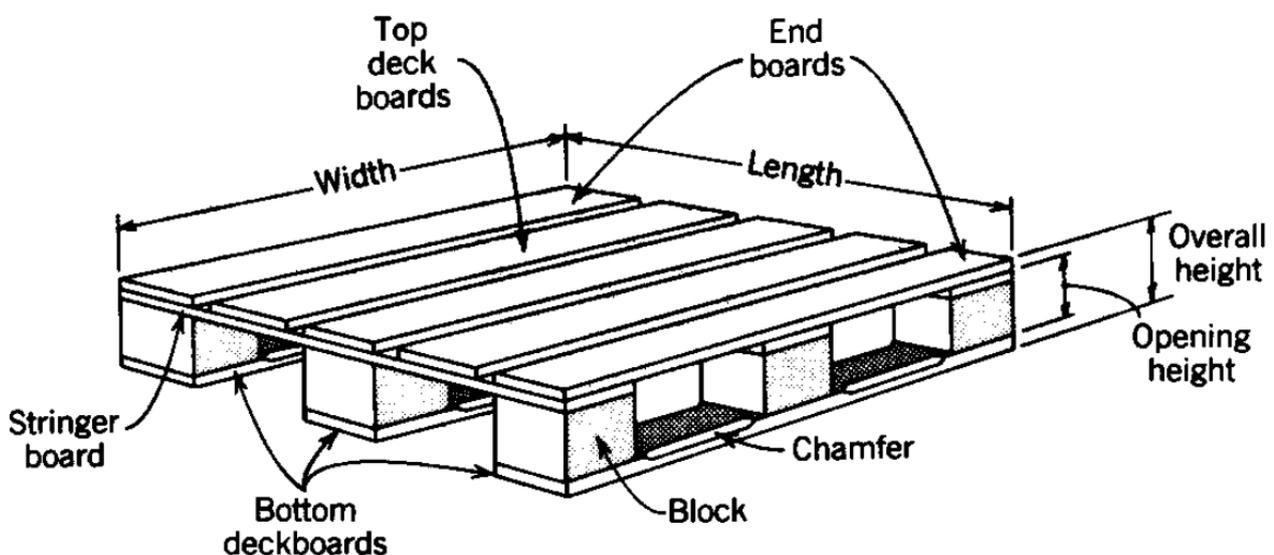
between top and bottom decks to permit the entry of mechanical handling devices.

- Flush stringer pallets- outside stringers are flush with the ends of the deck boards.

### Preferred Type:

All wooden pallets must be double-face, non-reversible wood construction and be of Block design. Per DIN 15146 120cm (L) X 80cm (W). Roche Diagnostics must approve any intended deviations.

Note: If international product only, Euro EPAL pallets are to be used.



Plastic pallets are permitted only with prior approval from Roche Receiving & Procurement, and must meet the following criteria:

- They must meet the dimensions for Standard Euro pallets Euro skids 120cm (L) X 80cm (W)
- They must be sturdy enough for basic transportation requirements.
- They must be sturdy enough to meet minimum material movements after delivery.

The basic outer dimensions of pallets must be maintained. Protrusions and overhangs must be avoided. All shipping units must be packed by SUPPLIER in a manner which is safe for transportation and protected from unauthorized access. Packing items are combined to form a safe unit on the shipping unit, and safeguarded against slippage in transit. At least the top layer must be covered. Available label pockets must be used. Tags must be attached to returnable packaging by means of easily removable, residue-free adhesive spots or adhesive tape. Tags must not be glued onto

returnable packaging. In the case of deliveries in small load carriers on pallets the top layer must form a single, even plane. The undamaged condition of pallets and box pallets (e.g. in accordance with the exchange criteria of the European Pallet Association EPAL (Internet: <http://www.epal-pallets.org> ) and other containers must be ensured.

The packaging must be clean. Compliance with Roche-specific cleanliness regulations and conditions in the delivery and production areas must be ensured. Special requirements apply to electrostatic sensitive devices.

Compliance with FDA, DIN and Roche standards where applicable must be ensured. Mixed consignments are permitted in principle, unless otherwise agreed. The number of mixed consignments should be kept to a minimum. Identical items should be distributed across the smallest possible number of shipping units.

## 5 Labelling

Material(s) in a container/pallet or box, unless otherwise stated in the Material Specification, must be identified individually with: The Roche Diagnostics Material Number (According to Product specification), Part Description in English, Lot or Batch/Serial Number (10 digit maximum, if applicable), quantity, Temperature Storage Conditions (other than room temperature, if applicable), unit of measure and Expiration Date when applicable. The format of this information may vary by product. Items with serial number(s) should be identified on the container or box where applicable.

### 5.1 Minimum requirements on spare part labels:

- Label(s) shall be a minimum of 102 x 152mm and applied to one end of package. If carton is too small to support this label size, make appropriate to the size of the carton.
- All information must be both human readable and material number/Lot Number bar-coded.
- Labels must be white in color with bold black printing.
- Adhesive type can be pressure sensitive or dry gummed as long as adherence to the package is assured and application is wrinkle free.
- The barcode must be EAN 128 or code 128.

Labels must be adhered to one (1) side of the box/container.

- Logo: Roche (see Roche Guidelines / Corporate Design)
- Parts description in English
- Material number 11-digit visual as well as per barcode (EAN 128-90)
- (Material number 10-digit visual in brackets)
- Part-no. (manufacturer part number) visually shown
- Mark of reparable parts, X = part was already repaired
- Contents (number of pieces per package)
- Made in ..... (Country of origin)
- Lot No. (for lot- / serial number parts only) visual and per barcode ( EAN 128 – 10 resp. EAN 128 – 21), 10digit maximum
- Expiration Date (for batch managed parts and / or if necessary), Format: DD/MM/YYYY
- Temperature Storage Conditions (if necessary from product Specification, in Celsius)

		
<b>Diaphragm vacuum pump</b>		
Mat.No.	11561677001	EAN128 - 90
	(1561677001)	
Part. No.	707-2308	
Contents	1	
Made in ...	Lot# 12345678	EAN128 - 10/21

Any changes in labeling will only be accepted prior to written approval by RDG.

## 5.2 MARKING/COUNTRY OF ORIGIN

All spare parts produced, procured, or repaired by or for RDG, including "no charge" items provided or returned to RDG, must be marked with the appropriate country of origin. This includes finished products, sub-assemblies, parts, media recorded with software programs, manuals and tools. Each article must have the full English name of its country of origin marked on the article itself and on the packaging in which it is received.

For all articles, the country of origin marking requirements is as follows:

- On the immediate container (the innermost level of packaging in which the articles will be received)
- On the article itself (where physically possible)
- Conspicuous (can be easily seen with normal handling of the article or container)
- Legible (can be easily read by a person with normal eyesight)

- Indelible (resists fading)
- Permanent (survives normal distribution and handling)
- Indicating to the ultimate purchaser the full English name of the article's country of origin.

The country of origin must be included on the commercial invoice and packing list (delivery notice) and must be consistent with the country of origin marked on the product package (immediate container) and the article.

**The following wording should be used for country of origin marking. Any modification to this wording must be approved by RDG.**

- Made in xxx (where xxx is the full English name of the country of origin)
- Printed in xxx (where xxx is the full English name of the country where the material was printed. Allowable for printed material and publications only).
- Product of xxx; (where xxx is the full English name of the country where bond and assembly occurred).

No abbreviations, with the exception of UK for United Kingdom and US or USA for the United States of America, are acceptable. The 2 character ISO-3166 codes are not acceptable for marking articles or product packages (immediate containers).

### **Container Marking**

A product package (immediate container) is defined as the innermost level of packaging in which the articles will arrive at the ultimate purchaser. The immediate container must be marked with the full English name of the country of origin of the articles contained within it, using the same wording as the marking on the articles (see above for acceptable wording).

Some immediate containers contain merchandise of different origins. In such an instance, each article within the immediate container must be marked with its country of origin and the immediate container must include a marking statement which summarizes the countries of origin of the articles in the immediate container. The country of origin summary statement begins: "Contains merchandise from:..." and is followed by a list of the full English names of the countries of origin of the articles in the immediate container. The country of origin of the "essential character" (the article that provides the most important function or is the reason why a customer would buy a specific product) in the immediate container should be listed first. If the contents of the immediate container are invoiced as a single line item, the country of origin of the "essential character" must be the country of origin shown on the commercial invoice and the packing list.

Containers designed for or capable of reuse must be individually marked to indicate the country of origin of the container. Use the following marking on containers suitable for reuse: "Container made in xxx", where "xxx" is the full English name of the country of origin of the reusable container. If the

reusable container is not empty, and the reusable container is the immediate container, the reusable container must also be marked "Contents made in xxx" (where xxx is the full English name of the country of origin of the contents). Exception: if the contents are of US origin, use the wording in above for Articles Manufactured in the US.

In all instances, the country of origin marking must be in close proximity to any labeling which designates an address that is not the country of origin. All references to any country on a product or package cannot mislead or deceive the buyer as to the actual country of origin of the article.

No abbreviations, with the exception of UK for United Kingdom and US or USA for the United States of America, are acceptable.

2 character ISO-3166 codes are not acceptable for marking articles or immediate containers

## **6 Repaired Spare Parts / Material Reworks**

Reworked/Repaired material(s) returned to Roche Diagnostics must have all previous labeling removed and replaced with new labels. RA-Forms, RA Labels with RA Numbers on product, packaging have to be removed. The packing list must identify the load and/or items that are "reworked / repaired".

## **7 Batch Management**

One lot per shipment is required. Pallets or carton boxes of mixed lots should only be used if one lot is not sufficient to fill a pallet / carton boxes. Mixed pallets / carton boxes are to be labeled "Mixed Pallets" and noticeably segregated on pallet/ carton boxes for efficient handling by RDG. Materials with more than one temperature condition are not to be mixed on a single skid.

## **8 Delivery Address**

All spare parts should be shipped to:

**Roche Diagnostics GmbH  
Distribution Centre Spares  
Boehringer Str. 13  
68307 Mannheim  
Germany**

## **9 Glossary**

DCS	=	Distribution Centre Spares
GCS	=	Global Customer Support
RDG	=	Roche Diagnostics GmbH