B Medical Systems -
General supplier packaging and labelling requirements

1. Scope

This document aims at defining general requirements for packaging of parts delivered to B Medical Systems S.à r.l. from any of it's suppliers, unless defined otherwise.

2. Packaging design requirements

2.1. General requirements

The packaging must be designed to assure protection of the parts from alteration or damages during the customary conditions of processing, storage, handling and distribution. *It should be suitable for the nature of the product and take in consideration the environment conditions during transportations and storage in order to assure that quality is not deteriorated and properties are not affected.* Regardless of the type of packaging, the following criteria should be considered:

1. Safety of the personnel during packing, handling, distribution and transport
2. *Special requirements based on the nature of the product (e.g. ESD boxes, VCI bags, vacuum seal or silicon bags)*
3. Damage-free parts deliveries (no quality impairment)
4. Easy loading/unloading with conventional handling equipment (forklift…)
5. Stackability
6. Easy removal of the packing material by limiting the use of any adhesive components
7. Use of recyclable materials
8. No contamination of the product
9. Minimal use of disposal materials
10. Minimize the cost
11. Use as much as possible standard dimensions for packaging (see 2.4)
12. Maximize as much as possible the utilization of space in containers (see Table 12.5)

2.2. Requirements for the prevention of packaging waste

Packaging must be planned under economic and ecological aspects. The regulatory framework for packaging and packaging waste in the European Union is set forth in the Directive 94/62/EC, amended by the Directives 2004/12/EC, 2013/2/EU and 2015/720/EU, and should be considered in the design phase.

The waste management objectives of the environmental legislation include according to the ecological priorities:

1. Avoidance
2. Reduction (i.e. reuse through the use of reusable packaging. The disposable part should be reduced)
3. Recycling (i.e. use of recyclable environmentally friendly materials)

2.3. Labelling

The packaging must carry standardized symbols on handling needs according to ISO 780. Furthermore, a packaging label must be affixed which must contain at least following information:

1. Identification Part Number
2. Number of parts in the packaging
3. Manufacturing Date
4. Use limitations: Any limitations for the use of the parts, such as restricted lifetime, must be stated on all packaging units down to the smallest packaging
5. Product Description
6. If applicable, a barcode based on the Code 39 has to be used
7. Initial sample parts must be marked as such
8. Reusable packaging must be labelled as such
9. If the delivery consists out of more than 1 package, the total number of packages must be stated on every single package (1/x; 2/x … where x is the total amount of packages)

2.4. Standard dimensions and weights of palletized packaging

Table 1 summarizes the dimensional and weight requirements for palletized packaging.

Table 1: Standard dimensions and weight of palletized packaging

Width [mm]	1200
Length [mm]	800
Max height [mm]	1250
Max weight [kg]	1200

Parts, which are larger than the size specified above, must be delivered on a pallet that matches the part dimensions.

2.5. Maximum weight of single packaging

The weight of one single package must not exceed 15 kg. Any packages that exceeds this weight has to be delivered on a palette or similar allowing transport and handling with a fork lift truck.

2.6. Special and reusable packaging

All special and reusable packaging must be agreed with B Medical Systems purchasing department.

Reusable packaging that is B Medical Systems property may only be used to transport B Medical Systems parts. Any external use is to be excluded.

For Euro pallets, the general return terms apply.

3. Liability

The supplier is liable for all quality reduction that results of faulty or soiled packaging. Additional expenses due to violations of the packaging specifications, agreed with the B Medical Systems purchasing department, may be charged to the supplier and will be included in the supplier evaluation. If the supplier damages reusable packaging owned by B Medical Systems, which goes beyond the usual wear and tear, the costs may be passed on to the supplier.

4. References

European and National Legislation on Packaging and the Environment
European Parliament and Council Directive 94/62/EC on packaging and packaging waste
European Parliament and Council Directive 2004/12/EC – amending Directive 94/62/EC
Commission Directive 2013/2/EU – amending Annex I to Directive 94/62/EC
European Parliament and Council Directive 2015/720/EU – amending Directive 94/62/EC
European Parliament and Council Directive 2018/852/EU – amending Directive 94/62/EC