

## Material Safety Purchasing Conditions

(as of 05/2021)

For all deliveries and/or services, the supplier shall – without prejudice to any statutory and/or regulatory requirements applicable to its deliveries and/or services – comply with the following requirements (as far as relevant according to the type of delivery):

### Personal Protection Equipment

Personal protection equipment (PPE) must bear the CE mark pursuant to the relevant applicable laws and regulations valid at the time of the delivery (e.g. but not restricted to, the PPE Regulation (2016/425/EU) or the German PPE Regulation Implementing Act (PSA-DG)). Personal protection equipment must be accompanied at delivery by written information or instructions from the manufacturer, drawn up in the German language, pursuant to the relevant applicable laws and regulations valid at the time of delivery (e.g., but not exclusively, in accordance with Point 1.4 of Annex II of the PPE Regulation (2016/425/EU)).

### Machinery

Machinery must, where applicable, comply with the following European Directives in the relevant applicable version valid at the time of the delivery:

- Machine Directive (2006/42/EC),
- Low Voltage Directive (2014/35/EU),
- EMC Directive (2014/30/EU),
- other applicable Community Directives,

as well as all harmonized European standards in force. In the absence of harmonized European standards for any machine ordered, the supplier undertakes to follow the German standards and technical specifications. In the event of deviation from harmonized European standards or German standards and technical specifications, the supplier shall document and demonstrate that the same degree of safety was attained in a different manner.

The aforementioned obligations of the supplier include that:

- machines ready for use are fitted with the CE mark,
- machines bearing the CE mark are accompanied by an EC declaration of conformity pursuant to the relevant applicable laws and regulations valid at the time of the delivery (e.g. but not restricted to Annex II 1. A. of Machine Directive 2006/42/EC) a declaration in the German language, in which all the relevant standards complied with are also set forth,
- incomplete machines must be accompanied by the manufacturer's declaration concerning the installation of an incomplete machine pursuant to the relevant applicable laws and regulations valid at the time of the delivery (e.g. but not restricted to Annex II 1. B. of Machine Directive 2006/42/EC) instead,
- a safety component within the meaning of the Machine Directive within the meaning of the EC declaration of conformity and the CE mark and if applicable the type approval or comprehensive quality assurance measures pursuant to the relevant applicable laws and regulations valid at the time of the delivery (e.g. but not restricted to Machine Directive 2006/42/EC) be provided and/or proven instead,
- for technical working materials potentially subject to EC type approvals, the certification of an approved Testing and Certification Body be submitted,
- instructions for use pursuant to the relevant applicable laws and regulations valid at the time of the delivery (e.g. but not restricted to Machine Directive 2006/42/EC), drawn up in the German language, also be supplied; in particular, the stipulated noise emission values are to be determined and documented. This shall also apply to incompletely delivered machines,
- to machines or incomplete machines, where technical documentation pursuant to the relevant applicable laws and regulations valid at the time of the delivery (e.g. but not restricted to Annex VII of Machine Directive 2006/42/EC), shall also be supplied instead.

The following additional safety relevant documents for the machine shall also be made available by the supplier:

- test certificates in respect to electrical safety (grounding conductor resistance, insulation resistance) for machines when installed by the supplier at Miltenyi Biotec B.V. & Co. KG;
- a risk assessment pursuant to the relevant applicable laws and regulations valid at the time of the delivery (e.g. but not restricted to Annex I No. 1 of Machine Directive 2006/42/EC).

For machines assembled by the supplier at Miltenyi Biotec B.V. & Co. KG it is agreed that following assembly and together with a representative of the pertinent technical department of Miltenyi Biotec B.V. & Co. KG the machine shall be subjected to a safety test and the appropriate report shall be drawn up. The following shall, in particular, be verified:

- the completeness of protective equipment,
- the efficacy of protective equipment,
- the completeness of the accompanying technical documentation.

Incomplete machines:

The supplier shall be under the obligation to:

- accurately describe its scope of performance and delivery,
- provide Miltenyi Biotec B.V. & Co. KG with all necessary interface information to enable it to assess, plan and implement the scope of performance as concerns functional and safety add-ons,
- include the assembly instructions and declaration of installation pursuant to the relevant applicable laws and regulations valid at the time of the delivery (e.g. but not restricted to Article 13 Paragraph 2 of Machine Directive 2006/42/EC).

The above points shall also apply in regard to orders for used machines if such machines are imported into the European Economic Area from a third country.

As concerns orders for concatenated machines, the supplier shall assume responsibility for conformity unless otherwise agreed upon.

### **Electrical Operating Equipment (Related Components or Materials)**

Electrical equipment must, pursuant to the relevant applicable laws and regulations valid at the time of delivery (e.g. but not restricted to the Regulation concerning the marketing of electrical equipment for use within specific voltage ranges - 1. Regulation to the German Product Safety Act (1. ProdSV)), bear the CE mark.

Electrical equipment and components and/or materials intended for use in electrical equipment must also comply in particular with all laws and regulations on the restriction of certain substances in electrical and electronic equipment (e.g. Electrical and Electronic Equipment Substances Ordinance (ElektroStoffV) and RoHS Directive (2011/65/EU)), where relevant, applicable and valid at the time of delivery.

The supplier is also obliged to provide us, without being separately requested to do so, with an appropriate written statement confirming RoHS compliance in relation to the delivery (including in relation to each component to be delivered) and to use appropriate systems and procedures to ensure the accuracy of the underlying findings.

### **Simple Pressure Vessels**

Simple pressure vessels (serial production welded containers for air or nitrogen with a maximum operating pressure of 30 bar and a maximum internal pressure product (Pressure x Volume) of 10,000 bar x l (further prerequisites for the qualification of a simple pressure vessel are subject to the relevant applicable and valid laws and regulations applicable at the time of the delivery, such as, but not limited to, the Regulation concerning the marketing of simple pressure vessels - 6. Regulation to the German Product Safety Act (6. ProdSV)) must bear the information in accordance with the relevant applicable laws and regulations valid at the time of delivery (e.g., but not limited to Annex III No. 1 of Directive 2014/29/EU) and the CE mark. Simple pressure vessels must be provided with instructions for use in the German language pursuant to the relevant applicable laws and regulations valid at the time of the delivery (e.g. but not restricted to Annex III No. 2 of Directive 2014/29/EU).

### **Gas Fired Equipment**

Gas fired equipment must be provided with the CE mark pursuant to the relevant applicable laws and regulations valid at the time of the delivery (e.g. but not restricted to EU Regulation 2016/426/EU). The equipment must be provided with the instructions for use in the German language pursuant to the relevant applicable laws and regulations valid at the time of the delivery (e.g. but not restricted to EU Regulation 2016/426/EU).

As concerns the delivery of technical working materials and parts thereof not falling under the provisions of the German Product Safety Act (ProdSG), the following shall be deemed agreed:

Technical working materials must, both according to the state of the art and pursuant to worker protection and accident prevention regulations, possess properties such that, when the materials are used as intended, users and third parties are protected against any and all hazards to life or health to the extent possible in view of such intended use. Any deviation from this rule requires a certification warranting the same level of safety.

### **Hazardous Substances**

Pursuant to the REACH Regulation (1907/2006/EC), as applicable in the relevant applicable version at the time of the delivery, the supplier is to provide a safety data sheet (SDS), drawn up in the German language and dated, if

- the substance or the mixture is dangerous,
- the substance is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB), or
- the substance is subject to authorization pursuant to the REACH Regulation (1907/2006/EC).

The supplier shall, without being separately requested to do so, provide us with a SDS even if a mixture does not meet the criteria to be classified as dangerous, but

- contains at least one substance posing human health or environmental hazards  
≥ 1 % by weight (for non-gaseous mixtures)  
≥ 0.2 % by volume (for gaseous mixtures),
- contains at least one PBT or vPvB substance or a substance subject to authorization  
≥ 0.1 % by weight (non-gaseous), or
- contains a substance for which there are community workplace exposure limits.

For repeat orders, and if the product has been modified in the meantime, the supplier shall, without being separately requested to do so, provide us with a current SDS.

#### **Articles pursuant to REACH Regulation (1907/2006/EC)**

The supplier is obliged to provide us with sufficient information for safe use of the article according to Article 33 of the REACH Regulation for articles containing one or more substances of very high concern (SVHC) according to Article 57 and 59 of the REACH Regulation in a concentration of more than 0.1% by mass (w/w).

The supplier is also obliged to inform us, without being separately requested to do so, should changes be made to the candidate list drawn up in accordance with Article 59 of the REACH Regulation (i.e. inclusion of further SVHC) which are relevant for the articles supplied to us.

Furthermore, the supplier shall provide us with the SCIP number of its notification to the SCIP database of the ECHA as required according to Article 9 of the Waste Framework Directive (Directive 2018/851/EU) if the article contains SVHCs in a concentration relevant for such notification. If a SCIP number is not yet available to the supplier, the supplier shall provide us with the TARIC/CN number in combination with the indication of the concentration of SVHCs present in the article.