

Annex and component for the ordering of working materials and substances – Material Safety Purchasing Conditions

(as of 06/2018)

The following technical working materials shall be considered to have been agreed upon further to acceptance of the order by the contractor in respect to the supply to Miltenyi Biotec GmbH with special safety requirements:

The technical working materials must be produced pursuant to the relevant applicable and valid laws and regulations pertaining at the time of the delivery (e.g. but not exclusively the German ProdSG [Produktsicherheitsgesetzes, Product Safety Law], the regulations promulgated on the basis of the ProdSG or the relevant EU regulations) concerning the safety requirements and other preconditions for placing on the market and may not endanger the life, health or other legal assets of users or third parties as set forth in statutory regulations.

This shall apply in particular to the following:

Personal protection equipment

The personal protection equipment (PPE) must bear the CE mark pursuant to the relevant applicable and valid laws and regulations pertaining at the time of the delivery (e.g. but not restricted to the regulation concerning the placing of personal protection equipment on the market – 8. ProdSV or after the placing on the market of the PPE from 21.04.2019 onwards pursuant to EU Regulation 2016/425). Personal protection equipment must be accompanied at delivery by written information from the manufacturer, drawn up in German, pursuant to the relevant applicable and valid laws and regulations pertaining at the time of delivery (e.g., but not exclusively in accordance with Point 1.4 of Annex II of Directive 89/686/EEC) or from 21.04.2019 after placing the personal protection equipment (PPE) on the market, it must be accompanied by written manufacturer's instructions in German in accordance with Point 1.4 of Annex II of EU Regulation 2016/425.

Machinery

The machinery must comply with the following European Directives as applicable, pursuant to in the relevant applicable version pertaining 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 contractor 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 contractor shall document and demonstrate that the same degree of safety was attained in a different manner.



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The aforementioned obligations of the contractor 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 and valid laws and regulations pertaining 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 and valid laws and regulations pertaining 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 and valid laws and regulations pertaining 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 and valid laws and regulations pertaining 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 and valid laws and regulations pertaining 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 contractor:

- Test certificates in respect to electrical safety (grounding conductor resistance, insulation resistance) for machines when installed by the contractor at Miltenyi Biotec GmbH.
- A risk assessment pursuant to the relevant applicable and valid laws and regulations pertaining 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 contractor at Miltenyi Biotec GmbH it is agreed that following assembly and together with a representative of the pertinent technical department of Miltenyi Biotec GmbH 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.



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Incomplete machines:

The contractor shall be under the obligation to:

- accurately describe its scope of performance and delivery,
- provide Miltenyi Biotec GmbH 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 and valid laws and regulations pertaining 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 contractor shall assume responsibility for conformity unless otherwise agreed upon.

Electrical operating equipment

Pursuant to the relevant applicable and valid laws and regulations pertaining at the time of the delivery (e.g. but not restricted to the regulation concerning the marketing of electrical equipment for use within specific voltage ranges) [Verordnung über die Bereitstellung elektrischer Betriebsmittel zur Verwendung innerhalb bestimmter Spannungsgrenzen auf dem Markt]) such electrical equipment must bear the CE mark.

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 presence of a simple pressure vessel cf. 6. GSGV)) must, pursuant to the Sixth Regulation concerning the Product and Devices Safety Act (Regulation concerning the marketing of simple pressure vessels [Verordnung über die Bereitstellung von einfachen Druckbehältern auf dem Markt – 6. ProdSV]), be provided with the CE mark pursuant to the relevant applicable and valid laws and regulations pertaining at the time of the delivery (e.g. but not restricted to Annex III No. 1 of Directive 2014/29/EU). Simple pressure vessels must be provided with instructions for use in the German language pursuant to the relevant applicable and valid laws and regulations pertaining 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 and valid laws and regulations pertaining 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 and valid laws and regulations pertaining at the time of the delivery (e.g. but not restricted to EU Regulation 2016/426/EU).



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The following shall consider to be agreed upon as concerns supply of technical working materials and parts thereof not falling under the regulations pertaining to the ProdSG:

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.

The following shall be considered to have been agreed upon in regard to the supply of hazardous materials:

Pursuant to the REACH Regulation (Regulation (EC) No. 1907/2006) as applicable, in the relevant applicable version at the time of the delivery, the contractor is to provide a safety data sheet (SDS), drawn up in German 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 REACH.

The contractor must, of its own accord, provide 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.

With repeat orders and if the product has been modified, the supplier must, of its own accord, provide a current Material Safety Data Sheet.

The above obligations are an integral part of the Agreement. Non-compliance therewith shall constitute a default in proper performance. Without prejudice to any warranties, we reserve the right to assert further claims for compensation resulting from consequences arising out of such default.