Supplier requirements “Gleason CE process”

1. Requirements for occupational safety, health protection and product safety

It is expected that the product to be delivered complies with the national, European and international regulations regarding occupational safety, health protection and product safety to the degree that they apply to it. In particular, these include all applicable prescriptions, laws, directives, standards, regulations, white papers, etc., such as:

- Product Safety Act
- EC Machine Directive
- BGV (German Trade Association Regulations)
- BGR (German Trade Association Rules)
- BGI (German Trade Association Information)
- ASR (Occupational Safety Guidelines)
- VDE, TUV guidelines
- DIN, EN, ISO standards — unless other agreements have been made

The contractor hereby guarantees compliance with them.

2. EC directives

The current EU guidelines and the corresponding harmonized EN standards apply and must be used by the contractor, such as:

- Directive 2006/42/EC "Machinery Directive"
- Directive 2014/30/EU "Electromagnetic Compatibility"
- Directive 2014/35/EU "Low Voltage Directive"
- Directive 2014/68/EU “Pressure Equipment Directive"
- Directive 2014/29/EU “Pressure vessels"
- Directive 2013/35/EU "Electromagnetic Fields"
- DIN EN ISO 12100

- And all harmonized standards to be used by the contractor for the product, such as DIN EN 60204-1, DIN EN ISO 13849-1/2, DIN EN ISO 4413 or DIN EN ISO 4414, in the version valid at the time of first delivery according to the official journal of the European Union, and the EC/EU directive applying to the product.

- In particular, if applicable, the relevant C standard type such as ISO 16090-1 or ISO 16089, in the version valid at the time of delivery.

GLEASON explicitly points out to the contractors that the scope of application and the volume of documentation for machine directive 2006/42/EC has broadened and includes “incomplete machines”, among other things!

If the contractor’s product comes under the scope of the machine directive, a declaration according to

- Appendix II Part 1 A (**EC declaration of conformity**) **or**
- Appendix II Part 1 B (**declaration for incorporation of an incomplete machine**)

must be delivered and indicate the valid directives and standards used for the product.

Herein, it must be confirmed that the listed directives and standards were followed during construction and manufacturing, and are to be delivered in the German language and another language specified by GLEASON (usually the language of the operating manual) according to the points below:

1.) For machines, an operating manual with the minimum requirements according to Appendix I chapter 1.7.4 et seq.

2.) The risk assessment according to DIN EN ISO 12100 (ISO/TR 14121-2) upon delivery.

3.) For incomplete machines an assembly manual, unsolicited, according to Appendix VI and additionally or alternatively an operating manual according to the requirements of MRL Appendix I chapter 1.7.4 et seq. with installation notes when the product is delivered to GLEASON.

4.) For incomplete machines, a second set of the declaration of incorporation and assembly manual must be sent to the GLEASON “Technical Documentation” department at least 8 weeks before delivery to GLEASON.

5.) For safety functions based on risk assessment or components (SRP/CS) that are involved in safety functions, for delivered/incomplete machines, the following points must be met. For these, the necessary user data must be obtained from GLEASON. When GLEASON determines the safety functions, they must also be obtained.

5.1.) For complete implementation of safety functions and SRP/CS groups: A safety-related block diagram giving the characteristic values of the SRP/CS (safety-related parts of a control system). For incomplete safety functions, the calculated proof must be provided in “SET or Sistema” format. This also includes the documentation of measures against CCF.

5.2.) For individual SRP/CS the component characteristics must be delivered (such as MTTFd, B10d).

5.3.) The design principles and fault exclusions for the mechanical, electrical, hydraulic and pneumatic parts involved in safety functions must be coordinated with GLEASON's technical design department, documented in Microsoft Word format and handed over to GLEASON.

Explanations in brief

SRP/CS: Safety-related part of a control system. **CCF:** Common Cause Failure: Error with a common cause component characteristic value of SRP/CS: Statement of statistically foreseen life of a component. Statement generally as MTTFd, B10d, **PFH or PL:** Safety-related block diagram: Graphic representation of the effective SRP/CS during implementation of a safety function.

The "holistic approach" to the CE symbol is to be fully complied with in consideration of other relevant guidelines.

In the EC declaration of conformity, a CE symbol must be attached to the machine or product in every case.

3. EC machine guidelines for modifications with significant changes

For modifications to existing machines / machine systems that constitute a "significant change" within the meaning of the EC machine guidelines 2006/42/EC, the scope of the modification by the contractor must be performed as with a new machine per Appendix II Part 1 A; see point 15 in the previous paragraph.

4. EC machine guidelines for modifications with no significant changes

For modifications that are "not significant changes" within the meaning of the EC machine guidelines 2006/42/EC, the contractor must provide the exiting documentation completely and correctly and submit all test verifications based on the aforementioned guidelines and standards to the GLEASON "Technical Documentation" department after delivery of the relevant work.

Ludwigsburg, August 10, 2023

on behalf of Heinz Hautzinger
Machine Safety