

# DECLARATION OF CONFORMITY

## CERTIFIED HYGIENIC NUTS

# CE



NGI fundamentally adheres to all applicable directives and standards. All information is based on the current state of knowledge and is subject to change. We attentively follow the revisions and amendments to these directives and will design our products accordingly. This ensures that products from NGI are always in compliance with currently valid requirements.

Our product category is not covered by the scope of application of the EC directive for machinery. For this reason, they cannot be furnished with the CE marking in accordance with the EC directive for machinery.

NGI A/S, Virkelyst 3-7, 9400 Nørresundby, Denmark, hereby declares that the design is according to 3-A, USDA & EHEDG guidelines and regulations specified in the following.

Furthermore, we declare that the listed materials applied in our products comply with the demands for materials used within the food and pharmaceutical industries.



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### **Materials, Surface Roughness, Fabrication and Geometry**

Metallic surfaces are constructed from AISI 304 grade stainless steel and are corrosion resistant under the specified conditions of use including those of cleaning. The elastomeric components are constructed from FDA approved rubber material. All materials used are considered non-toxic and are non-absorbent.

All exposed metallic surfaces are finished to maximum surface roughness values of 0,8  $\mu\text{m}$  Ra. All elastomeric components and sealing washers are left as moulded with no hand trimming and all surfaces are considered smooth enough to ensure superior cleanability.

There are no exposed dissimilar metal-to-metal contact areas in the construction where galvanic corrosion could occur.

Hygienic seals permit access for easy cleaning with no inaccessible pockets or crevices.

There is no risk of exposed threads and no unsealed metal-to-metal joints in the finished construction.

All exposed surfaces have a smooth finish so that soil may be cleaned from the surface using manual cleaning techniques and be free of pits, folds, cracks, crevices, and other imperfections in the final fabricated form.

### **Drainability and Installation**

The levelling feet are designed to be self-draining and contain no horizontal ledges. Comprehensive instructions are provided containing detailed information to ensure compliance with the EHEDG design criteria.

The 3-A Sanitary Standard 88-00 requires that when leveling feet are properly mounted on the equipment, they shall provide a minimum clearance between the lowest part of the equipment and the floor of no less than 4.0 inches (102 mm) if the equipment outlines an area in which no point is more than 12.5 inches (318 mm) from its' nearest edge. If the equipment outlines an area in which any point is more than 12.5 inches (318 mm) from its' nearest edge the clearance shall be at least 6 inches (152 mm).

The EHEDG guideline recommends a minimum clearance between the equipment and the floor or wall of 300 mm for easy cleaning and inspection.

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### **Maintenance and Cleaning**

Cleaning instructions describe typical cleaning procedures with recommended maximum temperatures/pressures and stipulate the use of non-abrasive cleaning aids.

The design does not contain dead spaces and avoid accumulation of soil, microorganism's insects and other vermin in areas which cannot be easily cleaned.

### **Adhesives, Lubricants, Insulation and Signal Transfer Liquids**

Sealing and thread locking compounds used in the construction are non-toxic in the cured state.

No lubricants, insulation material or signal transfer liquids are used in the construction.

### **Standards and directives**

EN 1672-2:2005 Food machinery / General design principles/Part 2: Hygiene requirements. EN

ISO 14 159 2004 Safety of machinery – Hygiene requirements for the design of machinery.

Document 13 EHEDG guideline on the hygienic design of apparatus for open processes.

EHEDG Class I: The hygienic design criteria evaluation report concludes that the designs meet the criteria for hygienic equipment class I for components situated in the non-food area and are accessible for easy cleaning without dismantling.

3-A sanitary standard for machine levelling feet and supports.

USDA Guidelines for the sanitary design and fabrication of dairy processing equipment June 2001.

### **EU regulations**

852/2004 on the hygiene of foodstuffs.

853/2004 specific hygiene rules for food of animal origin.

854/2004 specific rules for the organization of official controls on products of animal origin intended for human consumption.

1935/2004 on materials and articles intended to come into contact with food.

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### The declaration of materials concerns the following Applications

**Application:**

Material type:

Compliance:

**Steel components, e.g. spindle, sleeve and cover for foot**

Stainless steel, AISI 304/A2 (X5CrNi18-10), Euro norm 1.4301.

By request: Stainless steel, AISI 316/A4 (X 5 CrNiMo 17 12 2), Euronorm 1.4401  
EN 10204 Type 2.2. NGI A/S states that the product is in compliance with the order with indication of results of nonspecific inspection.

NGI A/S has got EN 10204 type 3.1 inspection certificates on all material used in the products but not specified for each foot.

In the directive 94/9/EC, Equipment for potentially explosive atmospheres, also known as the ATEX directive, equipment without its own potential source of ignition are not covered, nor shall be marked according to the directive. However, NGI levelling feet are suitable for use in all ATEX zones.

**Application:**

Material type:

Hardness:

Color:

Range of temperature:

Storage:

Compliance:

GMP:

**Sealing ring between steel components for NGI's machine feet.**

Silicon rubber

60 Shore A

RAL 5010 (blue)

Min -60°C to Max +200°C

According to ISO 2230

FDA: Guideline 21 CFR 177.2600

RoHS 2: In accordance with the Directive 2011/65/EC OF EUROPEAN PARLIAMENT AND OF THE COUNCIL.

Good manufacturing process in accordance with 2023/2006 EC.