

To whom it may concern

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FDA approved hybrid bearings from CeramicSpeed

The machines used in food production, and their various subcomponents, must be approved for use in food production, taking into account the conditions they are exposed to. This applies if the component of the machine is or risk getting in contact with food. It is therefore important to be aware of the conditions under which a component is installed. A material can e.g. be approved for contact with food at normal temperatures, but not in relation to boiling.

In the CeramicSpeed Corrotec product line, the components in the bearing are approved for use in food production. The components are certified with FDA 21 CFR: Code of Federal Regulation, an area of legislation covering medicine and food in the United States. For some of the components, an additional EC No. 1935/2004 authorization is added, and more is expected to follow.

For each component, there is specific approvals, which can all be classed with FDA 21 CFR. A specification of the approvals for CeramicSpeed Corrotec product series can be seen in the table below:

Product line	Silicon Nitride balls	Lubrication	Cage	Inner and outer ring	Seals		Coatings	
					Stainless	Rubber	CorroCoat	WearCoat/ HardCoat
Corrotec FDA	X	X						
Corrotec FDA+	X	X	X	X	X	X	X	X

Corrotec FDA: This is the standard product, which has a minimum approval for balls and lubrication and the bearings can get in indirect contact with food.

Corrotec FDA+: This special line is the only one in the world, which has all components approved and the entire bearing is approved to come in direct contact with food.

Below is a list of the components, which are part of the CeramicSpeed hybrid bearings, and the set of approvals. As seen, all components comply with the US guidelines for food contact, and the hybrid bearing is therefore entirely safe to use in the food production.

Component	Material	Approval	Comment
Balls	Silicon Nitride (Si ₃ N ₄)	FCN	Approved for contact with all types of food under the conditions A to H in table 2
Lubrication	Klübersynth® UH1 14-222	NSF H1. In accordance with FDA 21 CFR § 178.3570	For use in lubrication of areas, that accidentally or inevitably come into contact with food.
Cage	Nylon 66	Tested in accordance with FDA 21 CFR § 177.1500	Can be used in machines that produce, handle or pack food.
Inner and outer rings	Stainless steel (AISI) 440C	FDA GRAS Has even passed the emigration test, see FDA 21 CFR § 175.300	Stainless steel type 440C * is considered safe to use in contact with food.
Sealing #1	Stainless steel (AISI) 440C	FDA GRAS Has even passed the emigration test, see FDA 21 CFR § 175.300	Stainless steel type 440C * is considered safe to use in contact with food.
Sealing #2	Rubber	FDA 21. CFR 177.2600 (Elastomeric) FDA 21.CFR 177.2400 (Perflouro elastomeric) FDA 21. CFR. 177.1500 (Plastics) Regulation EC1935/2004 European Alimentary (Elastomeric)	May be used in machines that produce food and where the bearings can get in indirect or direct contact with food.
Coating #1	CorroCoat	FCN EC No 1935/2004 Article 3.	Approved for contact with all types of food under conditions A to H in table 2
Coating #2	WearCoat, HardCoat	FCN EC No 1935/2004 Article 3.	Approved for contact with all types of food under conditions A to H in table 2

* Specific demands for stainless steel are required, particularly regarding heavy metal and surface finish.

FDA: Food and Drug Association

The US food administration.

FCN: Food Contact Notification

A statement from the FDA, which approves the use of a material in contact with food. The permit requires that the food is manufactured under one or more of the conditions specified in table 2.

NSF International: National Sanitation Foundation

Nonprofit organization that creates standards and define test in relation to food safety.

21 CFR: Code of Federal Regulation

The area of legislation covering medicine and food in the United States.

GRAS: Generally Recognized As Safe

Materials that FDA generally consider safe to use in connection with food.

EC No 1635/2004: European Commission

European legislation about materials that are exposed to food

Table 2 – Terms of use for hybrid bearings in the food production

- A. Sterilisation at high temperatures (e.g. temperatures above 100°C).
- B. Sterilisation with boiling water.
- C. Pasteurized at temperatures above 65°C.
- D. Pasteurized at temperatures below 65°C.
- E. Manufacturing and storage at room temperature. (No heat treatment in wrapping).
- F. Storage in refrigerator (No heat treatment in wrapping).
- G. Frozen storage (No heat treatment in wrapping).
- H. Storing frozen or refrigerated: Ready-made food, ready for use after heating in wrapping.

Best regards

CeramicSpeed Bearings A/S



Anders Thormann
Managing Director