



## DECLARATION OF CONFORMITY - FDA

Issued by: Danish Technological Institute  
Gregersensvej 9  
DK-2630 Taastrup

Product: PVD coatings of:  
- Chromium Nitride (CrN)  
- Diamond-Like Carbon (DLC)

Product description: Surface coatings applied by  
Physical Vapor Deposition  
(PVD)

Danish Technological Institute hereby declares that the above-mentioned coatings, when applied according to our specifications, are suitable for their intended use in contact with food, based on the requirements and assessments of the U.S. Food and Drug Administration (FDA).

**This declaration is based on the following:**

**1. FDA Opinion Letter:** The suitability of the CrN and DLC coatings for repeat-use food contact applications has been reviewed by the U.S. Food and Drug Administration. In an opinion letter dated April 23, 2019 (Ref: Pre-Notification Consultation (PNC) 002344), the FDA's Center for Food Safety & Applied Nutrition stated:  
"under the conditions described... we consider the CrN and DLC coatings acceptable for the intended use described in your inquiry and do not require premarket approval as a food additive..."

**2. Intended Use:** The coatings are intended for use as wear-protective surfaces on repeat-use tools and components in food processing and food packaging equipment (e.g., molds and dies). The conditions of use (e.g., moisture, temperature, pH) shall be limited to those in which the coatings remain stable, insoluble, chemically inert, and resistant to abrasion.

**3. Traceability:** Each coating process is fully traceable. A certificate of conformity can link a specific coating batch to a customer order, ensuring that an efficient recall can be performed if necessary.

Conclusion: Based on the direct assessment by the FDA, Danish Technological Institute confirms that the CrN and DLC coatings are suitable for repeat-use applications in food contact equipment and comply with the safety requirements as evaluated by the FDA.

**4. EU Declaration of Compliance:** Danish Technological Institute has issued a separate Declaration of Compliance for food contact for CrN and DLC PVD coatings. This declaration confirms compliance with Regulation (EU) 1935/2004, Regulation (EU) 2023/2006, Executive order, BEK no. 681 of 25 May 2020 and Council of Europe Resolution CM/Res(2013)9.

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