

Mitterteich, 2025-07-16

## CERTIFICATE OF NON-OBJECTION FOR THE USE OF SPECIAL GLASSES FROM SCHOTT FOR FOOD

SCHOTT glass types applicable for i.e. pharmaceutical primary packaging like

FIOLAX®, FIOLAX® Pro, BORO-8330™, DURAN®, DUROBAX®, ILLAX®, AR-GLAS®, NGCF

are special glasses, which have been in use for decades.

If the stipulations of the individual pharmacopoeia are fulfilled and the containers are correctly manufactured, they can be used for food without objection.

Glass does not release its constituents into food at levels harmful to human health or change food composition, taste and odor in an unacceptable way, hence it also complies with 'Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food'.

In the case of new developments, compatibility tests of course have to be carried out.

We hereby certify that the special glass tubing / rods have been produced by consistently using a Quality Management System according to ISO 9001:2015 and ISO 15378:2017 and as well as in accordance with our Technical Performance Specification / Technical Terms of Supply.

### Declaration of Conformity

The heavy metal content, e.g. lead, cadmium, mercury and hexavalent chromium of both our special glass tubing / rods and our packing are below 100 ppm, i.e. considerably below the limit values of the US and EU regulations (article 5, paragraph 4 of Regulation (EU) 2025/40).

The FDA classifies glass in general as GRAS (Generally Recognized as Safe).

Source: Federal Register/Vol 48, No. 27/Feb. 08.1983/page 5718, Rules and Regulations

### Citation:

"The agency has traditionally considered materials such as ceramics, glass, and stainless steel as GRAS for food-contact use, based on their safe history of common use as food-contact materials before 1958. However, because the use of these materials has been so widespread, the agency has never considered it necessary to list these materials as GRAS"

**SCHOTT AG**

**Business Unit Tubing**

Global Director Quality Management



Dr.-Ing. Karsten Hennig

**SCHOTT AG**

**Business Unit Tubing**

Senior Product Manager Pharma Tubing



Dr. Claudia Heini