

## **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®, BORO-8330™, DURAN®, DUROBAX®, ILLAX®, AR-GLAS®, NGCF, NGA  
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 odour 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 EC regulations (article 11 of stipulations 94/62/EC).

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"

**Business Unit Tubing  
SCHOTT AG, Site Mitterteich**

Director Quality Management  
Business Unit Tubing



Dr.-Ing. Karsten Hennig

**Business Unit Tubing  
SCHOTT AG, Site Mitterteich**

Product Manager  
Pharmaceutical Tubing



Dr. Claudia Heini