

Mitterteich, 2015-06-26

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

SCHOTT glass types for pharmaceutical primary packaging as
FIOLAX® , BORO-8330™ , DURAN® , ILLAX® , AR-Glas®
are special glasses which have been in use for decades.

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

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 Assurance System according to ISO 9001:2008, ISO 15378:2011 and as well as in accordance with our Technical Terms of Supply.

Declaration of Conformity

The heavy metal contents, e.g. lead, cadmium, mercury and hexavalent chromium of both our special glass tubing 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).

Origin:
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 Segment Tubing
SCHOTT AG, Site Mitterteich**

Director Quality Management
Site Mitterteich and
Business Segment Tubing

Dr. Karsten Hennig

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

Product Manager
Pharmaceutical Tubing

Dr. Bettine Boltres

F-PTR-1923 GB / index 2 / 10.04.2013 / TQ/KHig-M:Sdl

Source: Schott, 130410

Description: Technical terms of supply		Date : 210214		H:\NAFVORG\KD D_Technical terms of supply.doc		Par. KD:		Par. Dir:hge		Page : 312.205	
NAFVSM B.V. Marialaan 108, 6541 RP Nijmegen, Netherlands tel +31-24-377.46.70, www.nafvsm.com , e-mail:info.nl@nafvsm.com				NAFVSM S.A.S. Zone Industrielle, F-60570 Andeville, France Tel+33-3-44.52.64.90, www.nafvsm.com , e-mail:info.fr@nafvsm.com							