

Mitterteich, 2024-01-01

C E R T I F I C A T E

We hereby certify that the borosilicate glass tubing of BORO-8330™ has been produced by consistently using a Quality Management System according to ISO 9001:2015 and ISO 15378:2017 as well as in accordance with our *Technical Performance Specification*. BORO-8330™ meets the requirements of ASTM E 438, Type I, Class A as well as ISO 3585:1998.

The alkali release measured as per the glass grains test specified for type I glass according to current US-Pharmacopoeia typically ranges within the following values:

0.020 ± 0.005 ml 0.02 M HCl / 1 g glass

The upper limit for glass type I according to current USP (comparable: water resistance class 1 resp. HGB 1 according to ISO 719 and HGA 1 according to ISO 720) is:

0.1 ml 0.02 M HCl / 1 g glass

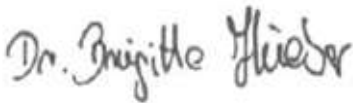
Borosilicate glass tubing BORO-8330™ therefore corresponds to the requirements of the current US Pharmacopoeia for type I glass as well as all other known pharmacopoeia (e.g. current Ph. Eur. and JP). Various tests on containers made from BORO-8330™ tubing have shown that the arsenic release is well below the limit value of 0.1 ppm As.

Declaration of Conformity

The heavy metal contents, e.g. lead, cadmium, mercury and hexavalent chromium of our BORO-8330™ tubing and our packing are below 100 ppm, i.e. considerably below the limit values of the US and EU regulations (article 11 of directive 94/62/EC).

Business Unit Tubing
SCHOTT AG, Site Mitterteich

Director Analytical Services



Dr.-Ing. Brigitte Hueber

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Global Director Quality Management



Dr.-Ing. Karsten Hennig