



Fraunhofer

**TESTED[®]
DEVICE**

Mettler-Toledo GmbH
PHD779lift

Report No. ME 2308-1443

DUPLICATE

Statement of
Qualification

Product series
Hygienic Design

Customer	Mettler-Toledo GmbH Im Langacher 44 8606 Greifensee Switzerland
Component tested	
Category:	Process Equipment
Subcategory:	Measuring Equipment
Product name:	PHD779lift Tested Products: <ul style="list-style-type: none">• PHD779lift 800x800 mm (manufacturing date: 8/2023)• PHD779lift 1500x1250mm (manufacturing date: 8/2023)

Assessment of conformity to GMP regulations as well as to EHEDG conception and design recommendations

Standards/Guidelines:	EU GMP Annex 1; EHEDG Doc. 8; DIN EN 1672-2; ISO 14159 The norms stated generally refer to the version valid at the time of the tests.
Assessment criteria:	<ul style="list-style-type: none">• Materials utilized• Material pairings• Installed components• Geometries of components used• Joining methods• Detailed constructional solutions• Manufacturing processes• Surface coatings/coating systems <p>The suitability of the operating utility for use in a GMP-conform manufacturing environment is ascertained on the basis of the assessment of these criteria with the aid of expert knowledge. The assessment focuses mainly on the avoidance of contamination as well as on the ability to clean and disinfect the operating utility.</p>

Test result / Classification	The PHD779lift series is principally suitable for use in hygienic areas up to the following GMP Class according to EU GMP Annex 1:		
	<table><tr><th>Suitability</th></tr><tr><td>up to GMP Class B</td></tr></table>	Suitability	up to GMP Class B
Suitability			
up to GMP Class B			

However, this only applies to the tested system in a resting state; an overall assessment of the manufacturing environment would need to be made after its installation.
The device may only be used in GMP Class B when it is certain that the geometry of device does not impair the quality of the laminar flow.

The measuring devices used for the qualification tests are calibrated at regular intervals; their results can be traced back to national and international standards. In cases where no national standards exist, the test procedure implemented complies with the technical regulations and norms applicable at the time of the test. The relevant documentation can be viewed on request at any time.

Detailed information and parameters of the test environment can be found in the Fraunhofer IPA test report.

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Department of Ultraclean Technology and Micromanufacturing	-- Report No. current document	-- Place, current date
Nobelstrasse 12 70569 Stuttgart Germany	on behalf of Dr.-Ing. Frank Bürger, Project Manager Fraunhofer IPA	