



Fraunhofer

TESTED[®] DEVICE

Rite-Hite Corporation
LITESPEED CLEANROOM
Report No. RI 2108-1247

Statement of
Qualification

Single product
Hygienic Design

Statement of Qualification · Single product

Customer	Rite-Hite Material Handling Equipment (Kunshan) Co., Ltd. 110 Donglong Road Kunshan Jiangsu 215300 China
Component tested	
Category:	Cleanroom Facilities
Subcategory:	Wall / Ceiling / Floor / Door
Product name:	LITESPEED CLEANROOM High Performance Door (manufacturing date: 5/7/2021; color: white; serial number: 136419; Height: 98.50inch; Width: 78.75 inch)

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 door LITESPEED CLEANROOM High Performance Door is principally suitable for use in hygienic areas up to the following GMP Class according to EU GMP Annex 1:		
	<table><tr><td>Suitability</td></tr><tr><td>up to GMP Class C</td></tr></table>	Suitability	up to GMP Class C
Suitability			
up to GMP Class C			

However, this recommendation only pertains to the operating utility when in a resting state. An overall assessment of the LITESPEED CLEANROOM can only be made after its installation in the production line.

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.