

Product Information

Use of zwickiLine Materials Testing Machines in Air Cleanliness Class 5 and 6 Cleanrooms

CTA: 46568 73334



Cleanroom requirements

The production of medical engineering or pharmaceutical products largely takes place in cleanrooms, where the concentration of airborne particles is kept as low as necessary. The EN ISO 14644 standard describes the requirements for cleanrooms and associated controlled environments. Depending on the size and number of particles present, a classification is established according to different cleanroom classes (see table).

Colandis GmbH in Kahla, Germany performed particle emission measurements on the zwickiLine Z0.5, Z1.0 and Z2.5 materials testing machines. [Based on these investigations, zwickiLine materials testing machines can be used in cleanrooms of air cleanliness class 6 to 9, according to DIN EN ISO 14644-1:2016, DIN EN ISO 14644-14 and VDI 2083-9.1]

Advantages and features

Cleanrooms in the pharmaceutical, medical engineering, biotechnology and food production industries have particularly strict requirements. These especially include reliable exclusion of risks from contamination through germs or other harmful substances.

ZwickRoell zwickiLine materials testing machines can be used in production and testing areas of cleanroom classes 5 and 6. Cleanroom suitability of the materials testing machines was validated according to DIN EN ISO 14644 1:2016-06, DIN EN ISO 14644-14 and VDI 2083-9.1.

- Testing can take place directly at the specimen removal location, without time consuming transfer of specimens from the cleanroom.
- Direct integration of the testing machine into the production process in the cleanroom (e.g. insulin pen testing) is possible.
- Biological specimens can be tested without contamination.

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Cleanroom suitability

Description	Item number
Confirmation of cleanroom suitability, air purity class 6 to DIN EN ISO 14644-1:2016, DIN EN ISO 14644-14 and VDI 2083-9.1, incl. certificate for zwickiLine Z0.5, Z1.0 und Z2.5. The cleanroom suitability of the zwickiLine has been verified on Z0.5, Z1.0 und Z2.5. Since all machines in the zwickiLine series Z0.5, Z1.0 und Z2.5 are identical in construction, we can also guarantee cleanroom suitability for the other construction heights.	1089901
Confirmation of cleanroom suitability, air purity class 5 to DIN EN ISO 14644-1:2016, DIN EN ISO 14644-14 and VDI 2083-9.1, incl. certificate for zwickiLine Z2.5+. The cleanroom suitability of the zwickiLine has been verified on a Z2.5+.	1089902

Cleanroom classes to DIN EN ISO 14644-1

Maximum allowable number of particles per m³

Class	0.1 µm	0.2 µm	0.3 µm	0.5 µm	1.0 µm	5.0 µm
ISO 1	10	2	-	-	-	-
ISO 2	100	24	10	4	-	-
ISO 3	1,000	237	102	35	8	-
ISO 4	10,000	2,370	1,020	352	83	-
ISO 5	100,000	23,700	10,200	3,520	832	29
ISO 6	1,000,000	237,000	102,000	35,200	8,320	293
ISO 7	-	-	-	352,000	83,200	2,930
ISO 8	-	-	-	3,520,000	832,000	29,300
ISO 9	-	-	-	35,200,000	8,320,000	293,000