REINHEITSKLASSENEINTEILUNG
nach EU-GMP Richtlinien ANNEX 1/ März 2008 und DIN EN ISO 14644-1/1999

Clean Room Class / Reinraum-Klasse	Discriptive according to CDER, June 1987: " Guidelinie on Sterile Drug Products by Aseptic Processing"	European Commission Annex 1, 2008 Manufacture of Sterile medical products						DIN EN ISO 14644-1/1999 Cleanrooms and associated environments Part 1: Classification of air cleanliness						
		at rest		in operation				at rest				in operation		
		Max. permitted Nu. of particles / m^3 equal to or above (/ft^3)				Max. number of colony forming units		Max. permitted Nu. of particles / m^3 equal to or above (/ft^3)				Max. permitted Nu. of particles / m^3 equal to or above (/ft^3)		
		≥ 0,5 µm	≥ 5 µm	≥ 0,5 µm	≥ 5 µm	CFU/m^3 (CFU/10ft^3)	descriptive	≥ 0,3 µm	≥ 0,5 µm	≥ 5 µm	descriptive	≥ 0,3 µm	≥ 0,5 µm	≥ 5 µm
Grade A[1]	Critical Areas	3.520	20	3.520	20	< 1	**ISO Class 5**	10.200	3.520	0	**ISO Class 5**	10.200	3.520	0
Grade B		3.520	29	352.000	2.900	10	**ISO Class 5**	10.200	3.520	29	**ISO Class 7**	102.000	352.000	2.930
Grade C	Controlled Areas [2]	352.000	2.900	3.520.000	29.000	100	**ISO Class 7**	102.000	352.000	2.930	**ISO Class 8**	---	3.520.000	29.300
Grade D+[3]		3.520.000	29.000	not defined	not defined	200	**ISO Class 8**	---	3.520.000	29.300	**ISO Class 8**	---	3.520.000	29.300
Grade D	Pharmaceutical (with local monitoring)	3.520.000	29.000	not defined	not defined	200	**ISO Class 8**	---	3.520.000	29.300	---	---	---	---

1. Air velocity for unidirectional air flow (laminar Flow): 0,36- 0,54 m/s + 20 %
2. Unnamed state after a short "clean up" period of 15 - 20 minutes
3. Additional requirement for particles in operation
4. Alle Angaben ohne Gewähr diese Tabelle ist rein informativ

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