

Certificate

PB-701084-16122021

For the (re-) qualification of cleanrooms regarding the requirements on the air purity in cleanrooms and clean zones in accordance with ISO 14644-1:2015 and with the european GMP guideline (attachment I).

Test location: adapta B.f.a.A. – ETA
Hochheid 2
4728 Hergenrath, Belgium

Date of test: 16.12.2021

Test objects: Operating mode: **Operation**

	Classification according to ISO 14644-1:2015	Degree of cleanliness according to EU-GMP-guideline -attachment I
Reinraum A1	Class 7	Grade C
Reinraum A2	Class 7	Grade C
Reinraum B	Class 7	Grade C
Laminar Flow Bereich	Class 7	Grade C
Büro	Class 7	Grade C
Flur	Class 8	Grade D
Materialschleuse Wareneingang	Class 8	Grade D
Materialschleuse Warenausgang	Class 8	Grade D

Client: adapta B.f.a.A. – ETA
Hochheid 2
4728 Hergenrath, Belgium

Date of requalification: December 2022

ISO 14644-1:2015

The cleanrooms and the clean zones fulfill the requirements regarding the classification of the air cleanliness according to the particle concentration limits

EU-GMP-guideline – attachment I

The cleanrooms and the clean zones correspond to the recommended microbiological limits in accordance with the established grade.

January 13, 2022

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