

Certificate

Nr.: TR-700779-04022021-E

For the (re-)qualification examination of cleanrooms in accordance with the requirements of DIN EN ISO 14644:2015 and EU GMP Guidelines Annex I.

Company:

Lohmann GmbH & Co. KG, Oberhütter Straße 48, 42857 Remscheid

Examination date:	04.02.2021
Validity Certificate:	04.02.2022
ISO-class:	8
GMP grade:	D
Test location:	Lohmann GmbH & Co. KG Oberhütter Straße 48 42857 Remscheid Cleanroom 1 & 2
Operation status:	in operation

DIN EN ISO 14644:2015

The requirements of DIN EN ISO 14644:2015 for permissible particle concentrations of the room air in the cleanliness ISO class 8 were kept faultless at all measuring points under operation status in operation. The clean rooms and clean room areas had differential pressure to the non controlled areas.

EU GMP

The microbiological contamination of the room air and the microbiological contamination of the surfaces in the clean rooms and clean rooms areas were fulfilled faultless at all measuring points the requirements of the EU GMP Guideline Grade D .

Reutlingen, the 12.02.2021

M.Sc. Isabel Matsch
Laboratory management




Dipl.-Ing. Frank Jürgen Matke
Technical direction