



To whom it may concern

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Preparation of Documents

MEGGLE Products:

- Lactose Monohydrate (USP-NF / Ph. Eur. / JP): GranuLac® 70 US, GranuLac® 140 US, GranuLac® 200 US
- Anhydrous Lactose (USP-NF / Ph. Eur. / JP): DuraLac® H

MEGGLE specifications are generated within a validated document management system.
Check and approval of documents is conducted via electronic signature.
Electronic signature meets the requirements of 21 CFR Part 11.

Product release is conducted and the issue of CoA's are manually generated upon review of each batch record, printed and signed.

Best regards

MEGGLE USA inc.



Dr. Gabriele Müller