



To whom it may concern

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Quality Unit / Regulatory Affairs

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GMP GDP EXCiPACT™

MEGGLE Product:

- Inhaler Grade Lactose Monohydrate (USP-NF / Ph. Eur. / JP): InhaLac® 400, InhaLac® 500

For product manufacturing at

Micronisierungs-Kontor Oberrot GmbH, Industriestr. 17, 74420 Oberrot, Germany

as the subcontracted production site as well as for release and distribution by

MEGGLE GmbH & Co. KG, Megglestr. 6-12, 83512 Wasserburg am Inn, Germany

of the above mentioned product:

GMP according to the Joint IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients and USP General Information Chapter <1078> is implemented at the subcontracted production site.

GDP principles, based on the IPEC Good Distribution Practices Guide for Pharmaceutical Excipients, are implemented at the distribution site.

MEGGLE GmbH & Co. KG is GMP and GDP certified according to EXCiPACT™ standard for the manufacturing, testing, storage and distribution of lactose and co-processed excipients used as pharmaceutical excipient or claimed for pharmaceutical use.

Best regards

MEGGLE GmbH & Co. KG

represented by MEGGLE Verwaltungs GmbH


Dr. Stefan Dreiheller