Packaging Compliance - Statement

Product group: Starch, Lactose, Inhalation, MCC, Biopharma and Superdisintegrants

All products manufactured by DFE Pharma GmbH & Co. KG

Dear Customer,

Herewith we declare that all packaging materials coming into direct contact with pharmaceutical products, used by DFE Pharma GmbH & Co.KG, comply with the relevant European legislation.

A Declaration of Compliance (DoC) as mentioned in regulation **(EC) 1935/2004** is obtained for all food contact materials/primary packaging materials. This DoC includes confirmation that the requirements of both regulation **(EC) 2023/2006** (basic quality system and GMP requirements) and regulation **(EC) 10/2011** (approved substance for use in plastic food contact materials including requirements for global and specific migration) are met.

Furthermore, the packaging materials comply with the requirements of **21 Code of Federal Regulations 177** in the United States of America.

This statement substitutes all previous versions issued for the brand names mentioned above.
We trust this information, which is made up to the best of our knowledge, will be helpful to you.

With kindest regards,

Name : Armand M. Janssen
Job title : QA Regulatory Affairs Officer
Signature :

This document is controlled by a validated, electronic system and is valid without signature.
The above facsimile signature is only for display.

DFE Pharma GmbH & Co. KG
Klever Strasse 187, 47574 Goch, Germany, P.O. Box 20 21 20, 47568 Goch, Germany, T. +49 2823 9288 770, F. +49 2823 9288 7799

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