

# GDP AUDIT CERTIFICATE

Audit Date  
**December 10<sup>th</sup> and 11<sup>th</sup> 2024**

Rephine hereby certifies that a Good Distribution Practices (GDP) audit was completed at the company's **Pharmaceuticals Division** facility located at

**INTER-HARZ & SCHMECHEL  
TRANSPORT**  
**Rostock-Koppel 10, 25365  
Klein Offenseth-Sparrieshoop**

The products in the audit scope encompassed **pharmaceutical products' distribution/storage/transport.**

The audit was carried out following the rules and methodology set forth in Rephine's Quality System based on **ISO 9001 & ISO 17020**

The results of this audit are described in a full report, filed by Rephine. The report is available to the interested parties, and bound by the terms and conditions of confidentiality, agreed with the audited

## Regulatory frame

EU Directive **2001/83/EC** (and amendments 2004/27/EC and 2011/62/EU), 21 CFR 210 & 211 and UK Human Medicines Regulations 2012 (SI 2012/1916)

## Reference to

Guidelines on the Principles of Good Distribution Practices for **Active Substances/ for Medicinal Products for Human Use**

Certificate Number  
**AUD-3789**

Validity for  
**3 years**

**José C. Vergara**  
**Technical Director**

**February 2025**

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