



June 27, 2024

BBF Sterilisationservice GmbH
Attention: Andrea Nolte-Karayel Ph.D.
CEO/Head of Packaging
Willy-Rüsch-Straße 10/1
71394 Kernen-Rommelshausen
Germany
Andrea.Nolte-Karayel@steriXpert.de

Dear Dr. Nolte-Karayel:

We are enclosing a copy of the Establishment Inspection Report (EIR) as a result of the inspection conducted at your premises located at Kernen-Rommelshausen, Germany, FEI number 3006017180, on March 4, 2024, through March 7, 2024, by the U.S. Food and Drug Administration (FDA). When the Agency concludes that an inspection is "closed," under 21 CFR 20.64(d)(3), it will release a copy of the EIR to the inspected establishment. This procedure is applicable to EIRs for inspections completed on or after April 1, 1997.

The Agency continually works to make its regulatory processes and activities more transparent for regulated industry. Releasing this EIR to you is part of that effort. The copy we are providing to you contains the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and 21 CFR Part 20. This, however, does not preclude you from requesting additional information available under FOIA.

Sincerely,

Carrie M. Mampilly Digitally signed by Carrie M.
Mampilly -S
Date: 2024.06.27 08:30:17 -04'00'

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Carrie M. Mampilly, MPH
Director, Division of Inspections & Surveillance
Office of Compliance & Biologics Quality
Center for Biologics Evaluation and Research

Enclosure