

Holder : YANTAI DEVELOPMENT AREA CHUANGJIA PHARMECEUTICAL
MACHINERY CO., LTD.
NO.1-1, DONGGUAN STREET, YANTAI CITY, CHINA

Manufacturer : YANTAI DEVELOPMENT AREA CHUANGJIA PHARMECEUTICAL
MACHINERY CO., LTD.
NO.1-1, DONGGUAN STREET, YANTAI CITY, CHINA

Product Description : TUBE FILLING AND SEALING MACHINE

Model(s) : RGF-80Z-C, RGF-100YC, RGF-100YZ, RGF-110R, RGF-110RZ, RGF-
220R, RGF-220Z

Requirements and Standard(s) : 2006/42/EC Machinery Directive
EN ISO 12100:2010, EN 415-10:2014, EN 415-3:2021, EN 60204-1:2018

Report No. : 086-03-026-08754

Date of Expiry : 22/05/2029

SWISS APPROVAL TECHNISCHE BEWERTUNG S.A. as a Third Party Certification Body, hereby certifies that the above mentioned products were witnessed by us during testing when applicable and we confirm that the product is in compliance with the above mentioned standards and requirements.

- This Certificate is issued in conjunction with the above mentioned Report and reflects findings during inspection in time and place only for the product and configuration described hereby and does not release buyer and/or seller from their contractual responsibilities.
- All modifications to the Technical File should be first submitted to our Company to ensure further validity of this attestation.

Henry Cai

Inspector

Henry Cai



Tzaferis
on behalf of Company

Tzaferis Meletis

Disclaimer: The inspection activities documented at this certificate and the relevant inspection report are not in the scope of SWISS APPROVAL TECHNISCHE BEWERTUNG Notification under harmonized Union product legislation, as notified by the competent authorities and listed in the Commission's NANDO information system and **cannot** be in an area of harmonized Union product legislation which requires assessment by a notified body.

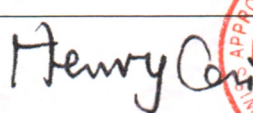
Holder/ manufacturer is **not permitted** to use SWISS APPROVAL TECHNISCHE BEWERTUNG notification number.

Holder/ manufacturer is **not permitted** to bear and affix CE marking by using this certificate and its accompanying documentation. CE marking is only to be affixed after testing the product and performing the prescribed conformity assessment procedure or procedures according to the applicable Union harmonization legislation.

Reference: EUROPEAN COMMISSION – DIRECTORATE GENERAL FOR INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SMES NOTE FOR THE ATTENTION OF MARKET SURVEILLANCE AUTHORITIES AND NOTIFYING AUTHORITIES
Voluntary certification for products subject of EU technical harmonization legislation / Ref. Ares (2022) 5342894 – 14/09/2022

INSPECTION REPORT

IR No.: 086-03-011-08754
Date of issue: 29/05/2024

Project Name	01	Third Party Inspection
Owner	02	YANTAI DEVELOPMENT AREA CHUANGJIA PHARMECEUTICAL MACHINERY CO., LTD.
Contractor	03	YANTAI DEVELOPMENT AREA CHUANGJIA PHARMECEUTICAL MACHINERY CO., LTD.
Manufacturer Name & Address	04	YANTAI DEVELOPMENT AREA CHUANGJIA PHARMECEUTICAL MACHINERY CO., LTD. NO.1-1, DONGGUAN STREET, YANTAI CITY, CHINA
Directive Applied / Module	05	2006/42/EC Machinery Directive Assessment of conformity with internal production control
Product Risk Category	06	Non annex IV of 2006/42/EC
Subject of inspection	07	TUBE FILLING AND SEALING MACHINE RGF-80Z-C, RGF-100YC, RGF-100YZ, RGF-110R, RGF-110RZ, RGF-220R, RGF-220Z
Place of inspection	08	Yantai, China
Date of inspection	09	15/05/2024
Requirements / Specifications / Norms	10	EN ISO 12100:2010, EN 415-10:2014, EN 415-3:2021, EN 60204-1:2018
Inspection activities	11	Audit of technical documents from the manufacturer; EHSR and Risk assessment; Inspection and tests of machine sample; Rectification and non-conformity closed; EC Declaration signed by manufacturer.
Inspection Remarks	12	It is recommended to issue the certificate of conformity in compliance with the requirements for documentation specified in Annex VII, part A; the Essential Health and Safety Requirements in Annex I of the European Parliament and of the Council on Machinery (2006/42/EC); and relevant harmonized standards.
Inspector (Name & Signature)	13	 Henry Cai
Attachments (Photos, docs, etc)	14	Technical Construction File No. TCF-CJ240505, Version 0; The technical files including general brief of products, user manual, mechanical and electrical drawings, EHSR, Risk assessment, CE data plate, declaration of conformity, etc.