



# CERTIFICATE



This is to certify that

## OPTIMA

### OPTIMA packaging group GmbH

Steinbeisweg 20  
74523 Schwäbisch Hall  
Germany

with the organizational units/sites as listed in the annex  
has implemented and maintains a **Quality Management System**.

#### Scope:

Development, manufacturing, sale and service of filling and packaging machines as well as occasionally converters (Life Science) with corporate services at the location Schwäbisch Hall – including Human Resources Department, Accountancy, Controlling, Purchasing Department, IT, Marketing, Legal Department, Coordination Department for

- Pharma (Pharmaceutical products and diagnostic / sterile and nonsterile liquids and powders)
- Consumer, (Food, chemicals and cosmetics / liquid, powdery or single items)
- Nonwovens (sanitary nonwovens products)
- Life Science (medical and pharmaceutical product / liquid coating and web treatment)

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

## ISO 9001 : 2015

Certificate registration no. 004830 QM15  
Valid from 2024-05-02  
Valid until 2027-04-25  
Date of certification 2024-05-02



### DQS GmbH

Christian Gerling  
Managing Director

DQS IS A MEMBER OF





**Annex to certificate**  
**Registration No. 004830 QM15**

**OPTIMA packaging group GmbH**

Steinbeisweg 20  
74523 Schwäbisch Hall  
Germany

**Location**

**Scope**

**227617**  
**OPTIMA consumer GmbH**  
**Geschwister-Scholl-Straße 89**  
**74523 Schwäbisch Hall**  
**Germany**

Design, sale, manufacturing and servicing of filling and closing machines for the food, chemical and cosmetic industry; single systems and turnkey projects. Cleaning, dosing and closing as central functions. The product portfolio is completed by film treatment, cartoning, as well as automation and handling techniques together with control and barrier systems.

**004831**  
**OPTIMA pharma GmbH**  
**Otto-Hahn-Straße 1**  
**74523 Schwäbisch Hall**  
**Germany**

Design, sale, manufacturing and servicing of machines and complete turnkey systems for cleaning, sterilizing, filling, closing and assembly of pre-filled syringes, vials, bottles, carpules and special containers for the use of liquid and viscous pharmaceutical products. Sterilizable freeze-drying systems, loading and unloading systems for vials, ampules, syringes or bulk loading as well as cleanroom technology complete the product portfolio.

**278657**  
**OPTIMA life science GmbH**  
**Kolpingstraße 23**  
**74523 Schwäbisch Hall**  
**Germany**

Design, sale, manufacturing and servicing of combined manufacturing and packaging machines for medical and pharmaceutical products. Modular liquid coating systems, for example immunoassays, which may contain functions like dispensing, incubing, coding, code identification, ionization, suction and packaging. In the converting area, modular systems for the manufacturing and packaging of modern wound dressings are produced. Typical functions are unwinding, rewinding, cutting, web edge control, camera systems and the packaging of four-edge seal pouches.



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**Registration No. 004830 QM15**

**OPTIMA packaging group GmbH**

Steinbeisweg 20  
74523 Schwäbisch Hall  
Germany

**Location**

**Scope**

**371983**  
**OPTIMA pharma GmbH**  
**Vor dem Langen Loh 8**  
**35075 Gladenbach-Mornshausen**  
**Germany**

Design, sale, manufacturing and servicing of machines and complete turnkey systems for cleaning, sterilizing, filling, closing and assembly of pre-filled syringes, vials, bottles, carpules and special containers for the use of liquid and viscous pharmaceutical products. Sterilizable freeze-drying systems, loading and unloading systems for vials, ampules, syringes or bulk loading as well as cleanroom technology complete the product portfolio.

**490340**  
**OPTIMA manufacturing GmbH**  
**Steinbeisweg 20**  
**74523 Schwäbisch Hall**  
**Germany**

Manufacturing of parts as well as assembly of modules and components for filling and packaging machines, particularly for all companies of the Optima Packaging Group.

**531482**  
**OPTIMA materials management GmbH**  
**Alfred-Leikam-Straße 36**  
**74523 Schwäbisch Hall**  
**Germany**

Administration as well as planning and steering of the material flow within the Optima Packaging Group (materials management), regarding timing, quantities, spaces and costs. This also includes the processes and projects which target the complete supply chain entity.

**278653**  
**OPTIMA nonwovens GmbH**  
**Steinbeisweg 20**  
**74523 Schwäbisch Hall**  
**Germany**

Design, sale, manufacturing and servicing of packaging machines for sanitary nonwovens products. After infeeding of the product from the converters to the pallet ready to ship, the machines build product formations and pack them into plastic bags or folding boxes (primary packaging). Machines with grouping units for multipacks made of plastic or packed into cartons (secondary packaging). Palletizers form units ready for shipment (tertiary packaging) out of the secondary packaging units.



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**OPTIMA packaging group GmbH**

Steinbeisweg 20  
74523 Schwäbisch Hall  
Germany

**Location**

**Scope**

**31622469**  
**OPTIMA packaging group GmbH**  
**Alfred-Leikam Straße 25**  
**74523 Schwäbisch Hall**  
**Germany**

Development of filling and packaging machines with centralised services at the site in Schwäbisch Hall. - Including human resources, accounting, controlling, IT, marketing, legal, organisation - for the various divisions.

**31622470**  
**OPTIMA pharma GmbH**  
**Schmollerstraße 31+33**  
**74523 Schwäbisch Hall**  
**Germany**

Design, sale, manufacturing and servicing of machines and complete turnkey systems for cleaning, sterilizing, filling, closing and assembly of pre-filled syringes, vials, bottles, carpules and special containers for the use of liquid and viscous pharmaceutical products. Sterilizable freeze-drying systems, loading and unloading systems for vials, ampules, syringes or bulk loading as well as cleanroom technology complete the product portfolio.

**31622472**  
**OPTIMA pharma GmbH**  
**Geschwister-Scholl-Straße 90**  
**74523 Schwäbisch Hall**  
**Germany**

Design, sale, manufacturing and servicing of machines and complete turnkey systems for cleaning, sterilizing, filling, closing and assembly of pre-filled syringes, vials, bottles, carpules and special containers for the use of liquid and viscous pharmaceutical products. Sterilizable freeze-drying systems, loading and unloading systems for vials, ampules, syringes or bulk loading as well as cleanroom technology complete the product portfolio.

**31622018**  
**OPTIMA Pharma Containment GmbH**  
**Hauptstraße 99**  
**78244 Gottmadingen**  
**Germany**

Development, manufacturing and service of cleanroom equipment



**Annex to certificate**  
**Registration No. 004830 QM15**

**OPTIMA packaging group GmbH**

Steinbeisweg 20  
74523 Schwäbisch Hall  
Germany

**Location**

**370307**  
**OPTIMA pharma containment GmbH**  
**Bodmaner Straße 2**  
**78315 Radolfzell-Stahringen**  
**Germany**

**Scope**

Planning, sales, production and service of cleanroom technology systems and involvement in complete turnkey projects. The range of products includes isolators for filling machines, sterility testing isolators, glove testing systems, H2O2 decontamination locks, electron accelerators for the "e-Beam" sterilization system and gastight doors. Integration possibilities are extremely varied when filling aseptic liquids or powders, in connection with e-beam tunnels, hot air tunnels, lyophilising units, autoclaves and other aseptic processing systems.