



Samsung Medical Rubber Company Presentation

Your partner for primary rubber packaging components

We introduce the business and technology of Samsung Medical Rubber Co., Ltd., which has specialized in the production of pharmaceutical and medical rubber products since its establishment in 1979.

46 years since
founding

720 million units
produced annually

Operation of the new
factory in Hwaseong



INDEX

Company introduction deck

Contents

We will introduce the core business, production system, products, quality and traceability system, certifications, and patents in order.

01 Company Overview

Company Overview and Key Indicators

02 History

Growth Milestones and Technological Evolution

03 Organization / Manufacturing Process Process

Operational Structure and Production Flow

04 Product Portfolio

Major product lines and application areas

05 Customer Services

Silicone processing, packaging, inspection, and clean supply

06 Traceability / Certifications / Patents

Quality assurance and intellectual property

Company Overview

Specialized manufacturer of pharmaceutical and medical rubber products

Samsung Medical Rubber Co., Ltd. has specialized in the production of pharmaceutical rubber products since its establishment in March 1979. Under the company motto of “Health, Abundance, Fulfillment,” we contribute to the healthy lives of society and pursue the abundance and fulfillment of everyone.

1979

Year of
establishment

46

Years since
founding

7.2 Billion

Annual production
capacity(20mm Base)

9,082 m²

Site area

7,500 m²

Building area

Company Name: Samsung Medical Rubber Co., Ltd. |
CEO: Jaehak Jeong



Address

56, Jeongoksandan 4-gil, Seosin-
myeon,
Hwaseong-si, Gyeonggi-do, South
Korea (18554)

Homepage

www.samsungrubber.com

History

We have grown steadily, focusing on quality certification, patents, research and development, and the construction of new factories.

1979

Company established (Samsung Medical Rubber Co., Ltd.)

1998

ISO 9001 Certification

1999

Patent acquired for ETFE-coated stoppers

2000

Selected as an Excellent Technology-Competitive SME by the Korean government

2008

FDA DMF Type III Registration

2014

ISO 15378 Certification

2015

R&D: Extractable Test (Toxicon) Completion

2016

Completion and relocation to new Hwaseong factory

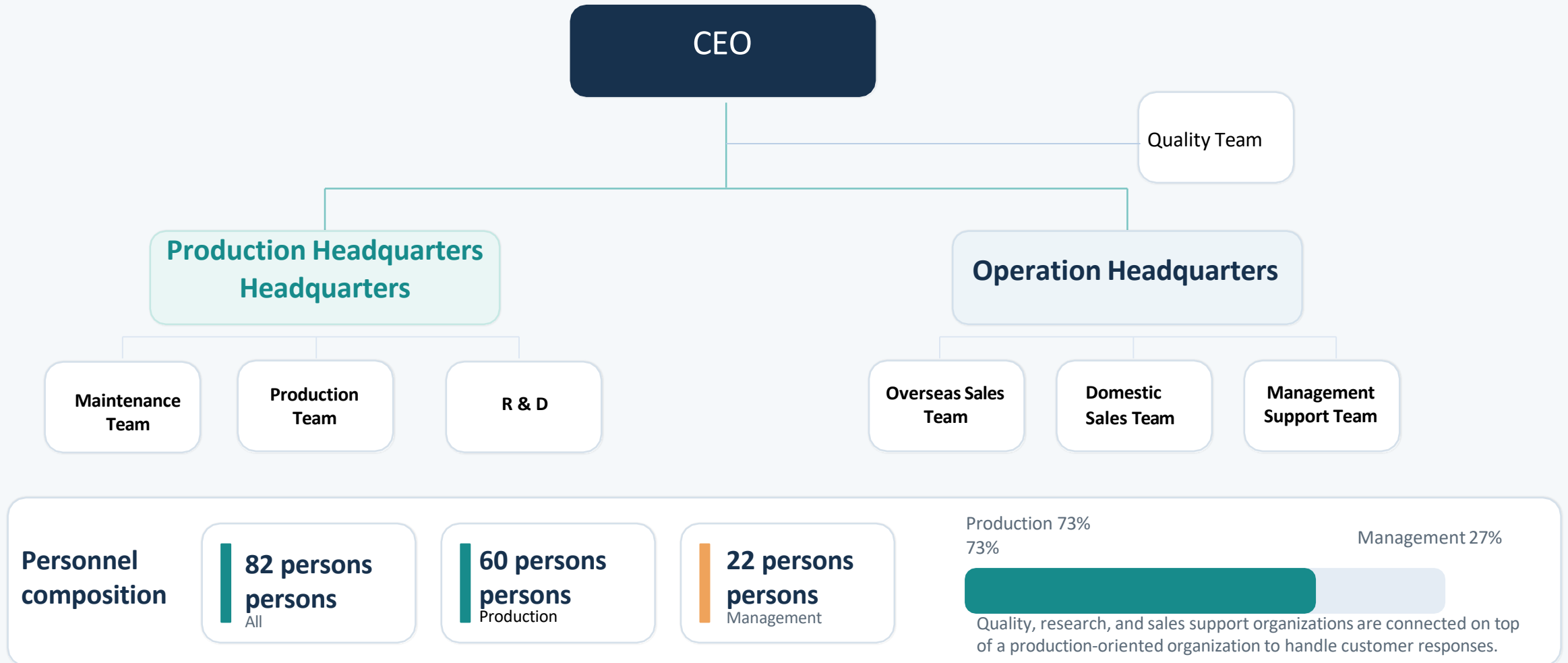
2020

Patent registered for manufacturing method of rubber blanks coated with fluoropolymer film on both top and bottom surfaces

2021~2023

Introduction of the True Traceability System™ and securing securing manufacturing technology for coating gaskets for gaskets for PFS/syringes

Organization



Manufacturing Process

We manage quality through a consistent process from formulation to final inspection.

Compounding →

Mixing →

Cutting →

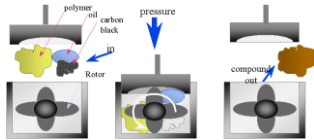
Forming →

Trimming →

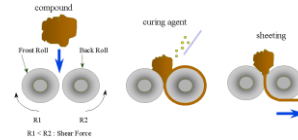
Washing →

Drying →

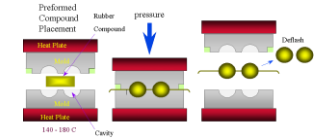
Final Inspection



Kneader Mixing



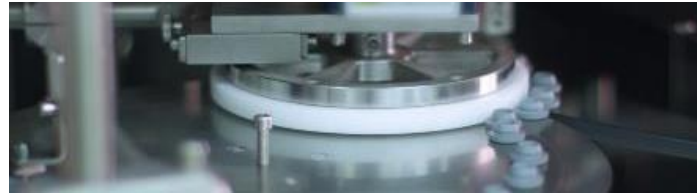
Roller Mixing



Forming



Washing / Drying



Final Inspection



Product Portfolio

We provide a wide range of key rubber components required for pharmaceutical packaging, from syringes and vials to IVs and PFS.



Serum Stopper



Freeze-drying Stopper



Film Coated Stopper



IV PORT DISC



Disposable Syringe GASKET



**PREFILLED SYRINGE
PLUNGER**

Product Portfolio | Major Product Group A

4-1 Serum Stopper



- Offering a wide range of designs
- High-performance products tailored to machine characteristics
- Shapes that meet customer requirements

4-2 Freeze-drying Stopper



- Customized formulations available
- Low gas/vapor permeability and low moisture absorption formulations
- Standard and custom designs
- 13mm / 15mm / 20mm / 32mm

4-3 Film Coated Stopper



- Exclusive film coating technology
- Domestic patent registered
- Fluorofilm coating
- Excellent barrier properties
- Suitable for injectable and intravenous use

Top / Bottom coating structure

Product Portfolio | Major Product Group B

4-4 Intravenous injection (IV PORT DISC)



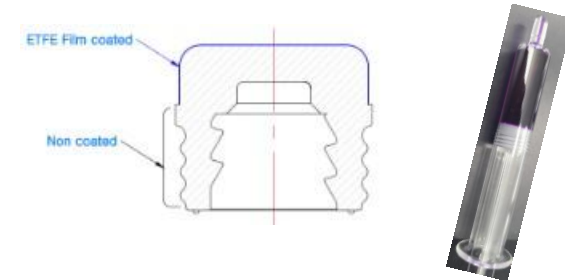
- Design for glass bottles / plastic bags
- Functional product featuring penetration and shape retention
- Quality meeting global standards

4-5 Disposable Syringe GASKET



- 100% Latex-free product
- 100% Latex product (Isoprene blend) available upon request
- High quality and long shelf life
- Sizes 0.3mL ~ 100mL

4-6 PLUNGER FOR PREFILLED SYRINGE



- Smooth Gliding Force
- Low Extractability
- ETFE Coated Section: Prevents contamination of liquid contact area
- Non-coated Section: Maintains sealing power

Customer Services

We provide services tailored to customer requirements, ranging from processing, packaging, inspection, testing, and clean supply.

5.1 Silicone treatment

SECT (Samsung Emulsion Coating Treatment)
SLPC (Silicone Low Particle Coating)
SLFC (Samsung Medical Fluid Coating Treatment)
Process Supplying

5.2 packaging

RTS / RTU / RTP
Clean Room ISO 5 / ISO 7

5.3 Special treatment

Gamma irradiation upon customer request

5.4 Camera inspection

SICV™ (Samsung Inspection Camera Vision)

5.5 Rubber fomulation verification

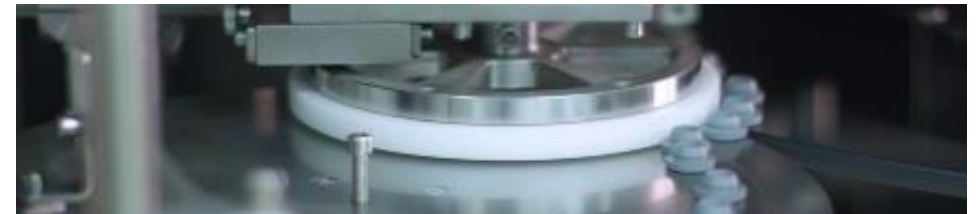
KP-USP-EP-JP Standard COA
Extractable Study / GLP test

5.6 Supply of clean rubber stoppers

Bioburden ≤ 5 CFU/100 cm²
Endotoxines ≤ 0.25 EU/ml
Particle $\leq 2.5 \sim 3.4$ PCI



Clean manufacturing / Washing and drying / Packaging environment

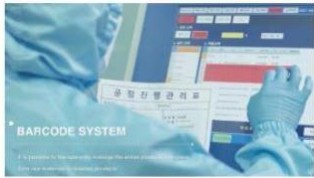


Camera Vision Inspection and Process Control

Traceability

6.1 MES- Based Transparent Management

Barcode-based MES system applied to all production processes, enabling full traceability from raw materials to finished products.



Barcode system



Production label

Raw Materials → Mixing/Forming →
Washing/Inspection → Finished Product

6.2 True Traceability System TM

Upon customer request, our patented Hybrid Laser Marking technology can be applied, enabling individual traceability of each and every product



마킹전

QR코드 및 식별번호 마킹후

Patent-based marking technology and an individual product identification system enable rapid traceability and response in the event of quality issues.

CERTIFICATES



ISO 15378 CERTIFICATE

BUREAU VERITAS, FRANCE



ISO 9001 CERTIFICATE

BUREAU VERITAS, FRANCE

Quality assurance system

- ISO 15378-based manufacturing process management
- Operation of ISO 9001-based quality management system
- Documentation and traceability system suitable for pharmaceutical and medical rubber parts
- Quality verification and assurance activities tailored to customer requirements

Manufacturing Process Guarantee

Quality Management System

PATENTS

Registered patent

- Patent No. 10-1772010 — Method for regenerating recycled rubber using electron beams and recycled rubber produced therefrom
- Patent No. 10-1810839 — Rubber stopper manufacturing apparatus and method for manufacturing a rubber stopper using the same
- Patent No. 10-1810839 — Medical rubber stopper and method for manufacturing the same

Application / Additional Technology

- Patent Application No. 10-2218574 — Method for marking rubber stoppers
- Patent Application No. 10-2163593 — Method for manufacturing a rubber stopper with upper and lower surfaces coated with fluoropolymer film
- Patent Application No. 10-2500336 — Method for manufacturing a fluoropolymer film-coated gasket (plunger) for PFS and syringes





Samsung Medical Rubber Co., Ltd. Growing Together with Customers

As a stable partner for pharmaceutical and medical rubber products, we will continue to provide customized customer support and maintain our quality competitiveness.

