



**FirstLine®:**  
DATWYLER'S MOST ADVANCED  
MANUFACTURING STANDARD



# HIGHEST MANUFACTURING STANDARD: **FirstLine**<sup>®</sup>

Datwyler's FirstLine<sup>®</sup> elastomer components offer the highest level of innovation, quality, and safety in the industry.

**Datwyler offers best-in-class packaging solutions for the pharmaceutical and biotech markets. To ensure patient safety, Datwyler's priority is to deliver safe and effective sealing solutions for drug packaging to its customers.**

Datwyler is dedicated to guaranteeing the highest level of quality and safety and continues to make investments aimed at meeting the ever-changing regulatory requirements of the industry. The highest industry demands are met with the company's most advanced manufacturing standard: FirstLine.

## **FirstLine<sup>®</sup> STANDARD FOR HIGH-QUALITY ELASTOMER COMPONENTS**

Datwyler's most advanced manufacturing standard, FirstLine, is specially designed to manufacture pharmaceutical rubber components for high-end pharmaceutical and biotech markets in a fully integrated cleanroom environment conforming to the highest industry standards. The FirstLine manufacturing concept is based on ultra-modern cleanroom technology, automated production cells, fully automated camera inspection, and a unique validated washing process. All facilities aligned with the FirstLine manufacturing standard are specially designed and operated under a zero-defect philosophy.

Datwyler's proprietary manufacturing standard, FirstLine<sup>®</sup>, is the most advanced manufacturing concept in the industry.

The FirstLine<sup>®</sup> manufacturing standard is specially designed to cater to the high-end pharmaceutical and biotech markets.





DATWYLER

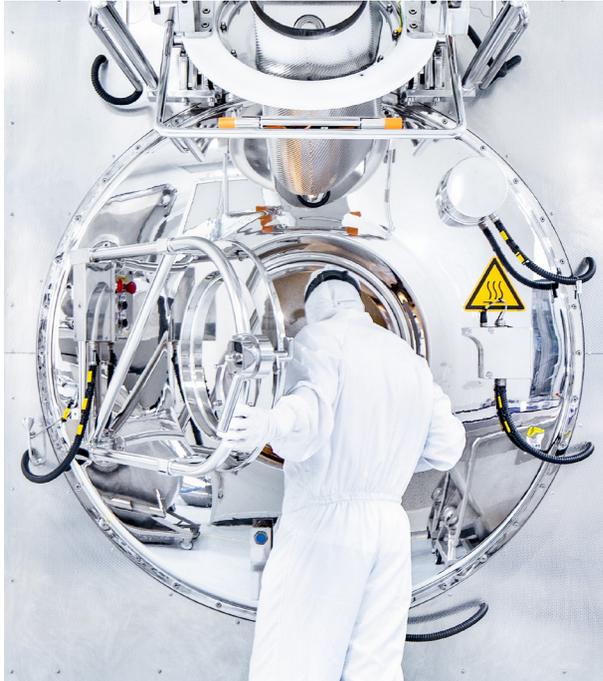
Vertical stainless steel machine with a control panel and safety features.

Horizontal stainless steel machine with rollers and a motor.

DATWYLER

Large horizontal stainless steel machine with multiple compartments and a control panel.

Horizontal stainless steel machine with a control panel and safety features.



The state-of-the-art cleanroom environment contributes to producing components with the lowest endotoxin, bioburden, particulate, and defect levels in the industry.

## ULTRA-MODERN ZONING CONCEPT CONTRIBUTES TO PATIENT SAFETY

Each zone has been meticulously designed and constructed in order to prevent bio-contamination and is equipped with material airlocks. State-of-the-art pass-through washing equipment has its automatic loading side in one zone and its automatic unloading side in a zone of even higher cleanliness.

The process flow, gowning protocols, personnel and material flow, as well as state-of-the-art automation processes all result in the lowest endotoxin, bioburden, particulate, and defect levels available in the industry. This innovative approach to manufacturing exceeds the most stringent quality standards of the European and US regulatory authorities and is certified according to ISO 15378.

## THE ADVANTAGES OF FirstLine®



### 1

#### Manufacturing concept

- Green-field and clean-building design
- Fully integrated Good Manufacturing Practice (GMP) environment
- Manufacturing zones with material airlocks and state-of-the-art pass-through washing and siliconization capabilities
- Coating capabilities
- Camera inspection capabilities

### 2

#### Benefits for the industry

- FirstLine produced components provide the lowest endotoxin, bioburden, particulate, and defect levels in the industry – both visible and subvisible
- The state-of-the-art equipment and techniques are all geared towards eliminating every possible form of contamination

### 3

#### Quality standards

- FirstLine is operated under a zero-defect philosophy
- Rational and lean production flows in all facilities
- Every element, i.e. particle measurement or air temperature, is independently monitored
- Certified according to ISO 15378 standards and subject to multiple validation procedures

**EXCLUSIVE FirstLine® PRODUCTS:  
PROPRIETARY FLUOROPOLYMER SPRAY COATED  
ELASTOMERS**

The company's most complex elastomer components are coated with Datwyler's proprietary fluoropolymer spray coating. The coated components are exclusively manufactured in facilities incorporating the FirstLine standard. They are used in pharmaceutical containers and prefilled syringes, particularly for biologics and biosimilars. Due to their total fluoropolymer coating, they prevent any interaction with the drugs.

The spray coating provides barrier properties and eliminates the closure as a source of silicone oil-based subvisible particles. The coated plungers and stoppers are manufactured using a proprietary, flexible, fluoropolymer spray coating technology. The technology is designed to (1) be an inert barrier and (2) impart a low coefficient of friction for non-siliconized prefilled syringe plungers. It is currently the best performing fluoropolymer coating technology addressing the compatibility and performance challenges of the biologics industry and beyond.

**DATWYLER'S  
PRODUCTION STANDARDS:  
CATERING TO THE CUSTOMER'S  
INDIVIDUAL NEEDS**

**FirstLine®**

The highest level of innovation, quality, and safety in the elastomeric pharma industry, designed for biotech and high-end pharmaceutical markets

**ADVANCED**

The proven and reliable solution matching the quality and regulatory needs of the pharmaceutical market

**ESSENTIAL**

The dedicated answer to medical market needs

Please read more about Datwyler's coating technologies in the Coated Sealing Solutions brochure.



Exclusively manufactured in FirstLine® aligned facilities: Datwyler's proprietary fluoropolymer spray coated components for high-end pharmaceuticals and biotech drugs.

## GLOBAL PRODUCTION FOOTPRINT

Datwyler's global manufacturing set-up, with local and regional presence, guarantees identical quality standards on a global level. The company meets its customers' needs for flexible supply chains and risk mitigation plans to ensure business continuity. FirstLine aligned facilities are strategically located in Belgium, India, and the United States, catering to the European, American, and Asia Pacific markets. Datwyler continues to invest in increasing its production quality level and capacity output.



Datwyler's global manufacturing footprint for the healthcare industry: Datwyler is where its customers are.



Based on ultra-modern cleanroom technology with automated production cells, fully automated camera inspection, and a unique validated washing process, Datwyler ensures the highest level of cleanliness.



The FirstLine® concept includes high-level camera inspection to detect and remove defects before Datwyler's products are packed and shipped to its customers.



Datwyler's way of living a zero-defect philosophy: FirstLine®.

**Datwyler Sealing Solutions is a leading industrial supplier and a key player in the global healthcare industry with a strong sense of future trends and the ability to set new standards. Datwyler offers state-of-the-art solutions for parenteral packaging with more than 100 years of multi-industry experience.**

Partnering with the world's top pharmaceutical and medical companies, Datwyler stands by its mission to improve patients' lives by constantly striving for zero defects in all its products. The company's state-of-the-art cleanroom manufacturing technologies exceed the most stringent industry requirements.

As a solution partner, Datwyler assists its customers in mastering the challenges of global healthcare and helps them act on opportunities of new and personal therapies.

Find out more about Datwyler's pharmaceutical and biotech solutions in other brochures:

Sealing Solutions for Healthcare  
Product Portfolio  
Sealing Solutions for Vials  
Sealing Solutions for Prefilled Syringes  
Sealing Solutions for Cartridges  
Coated Sealing Solutions  
DuraCoat™ Combiseals  
Packaging & Sterilization  
Services  
StarterPack™



[www.datwyler.com](http://www.datwyler.com)

December 2021

The information contained in this brochure is for general information purposes only. Datwyler assumes no responsibility for errors or omissions in the contents of the brochure. In no event shall Datwyler be liable for any special, direct, indirect, consequential, or incidental damages or any damages whatsoever, whether in an action of contract, negligence or other tort, arising out of or in connection with the use of the contents of the brochure. Datwyler reserves the right to make additions, deletions, or modification to the contents of the brochure at any time without prior notice. All IP and all trademarks mentioned herein are the property of their respective owners. Photos: Scanderbeg Sauer, Scott Witalis, Studio Frog

