

AppliFlex

The Single-Use-Bioreactor from Applikon

- 🕒 real time measurement of pH, DO, T, agitation
- 🕒 accurate control of pH, DO, T, agitation
- 🕒 data logging & SCADA (21CFR part 11) available



AppliFlex System

- 🕒 validatable system (total)
- 🕒 standard available retrofit options
 - combination with 3rd party systems
 - connection with 3rd party controllers
- 🕒 standard present: qualified Support and Service (Applikon and Stedim)

AppliFlex is the result of the strong alliance between Applikon & Stedim, offering a range of reliable & fully controlled Single-Use-Bioreactor systems

The Single-Use-Bioreactor

AppliFlex bags are made of STEDIM 71 film. STEDIM 71 is a co-extruded six-layer film providing a strong structure with low gas permeability and high chemical resistance. The inner layer (EVAM®) in contact with the liquid, is extruded using EVA resin and laminated with the co-extruded high gas barrier structure without any adhesives. The film formulation does not contain any substance derived from animal sources.

STEDIM 71 is extensively tested to ensure the highest product quality:

Biocompatibility Testing

compliant with ISO 10993 and USP<88>

Physicochemical testing

with alcohol and water at 70°C (158°F) in accordance with USP<661>

Chemical Resistance

chemical studies to evaluate the physical resistance of bags, tubing and components to chemical reagents according to ASTM D543-95 guidelines.

Interaction Studies Container/Solution

to evaluate the migration of products from bags to typical reagents over the course of prolonged exposure.

Drug Master File (N°: 13014) is registered with the FDA. A letter of authorisation can be provided (to cross-reference the Stedim D.M.F.)



AppliFlex Rocker and Control System

The rocker is designed in compliance with CE guidelines and can be applied for a range of reactor volumes.

With the key-pad the frequency (rocking rate) and the tilt angle can be adjusted. Serial output of data (frequency and tilt angle) and remote control options are available as a standard.

The control system (pH, DO, T, rpm) is formed by the standard Applikon units ADI1010 and ADI1025. This includes pressure control (the bag is kept under constant pressure).

The sensors (pH, DO, T) are designed for single-use. Manufactured according to the highest quality standards and backed by 50 years of sensor experience, an accurate and reliable measurement of important parameters is guaranteed.

The combination of the bioreactor bag with sensors and control system offers great opportunities for cGMP applications.

Tests prove that the system has a high $k_L a$.

Ordering information Parts

Z650002010	20L total volume, single-use-bioreactor, sterile (gamma irradiated), WV 1-10L
Z100000310	sensor module (pH/DO/T), sterile (gamma irradiated)
Z350002010	bag holder
Z350002020	holder assembly
Z550004510	rocker
Z510100010	ADI 1010 Bio Controller
Z310250010/SUB	ADI 1025 Bio Console

A complete AppliFlex system will be delivered with BioXpert Lite data acquisition software.

The system can be easily upgraded with BioXpert XP (21CFR part 11).



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