



**BIOCONNECT**<sup>®</sup>

VWR SINGLE-USE

# Certificate of Compliance



**300L 2D Tankliner**  
1 pc. **JMSCYBOV005600**

Sterile Gamma



**NON PYROGENIC / PYROGENFREI**  
**SINGLE USE**

Do not use if package is damaged, caps are loose or if any leak is found.



Nicht verwenden, falls Verpackung beschädigt ist, der Verschluss fehlt oder das Produkt ausgelaufen ist.



20170614-4



2017/06



2020/06

Certificate No.: 20170614-4

### Good Manufacturing Practices

This product was manufactured in a facility that adheres to Good Manufacturing Practices.

### ISO Quality Standard

This product was manufactured in a facility whose Quality Management System is approved by an accredited notified body to the ISO9001:2008 and ISO13485:2003.

### Validated manufacturing process

This product was manufactured, according to the product specifications, using a validated manufacturing process. Principles of statistical process control and determination of process capability have been applied to critical variables in the manufacturing process. In-process controls are in place to assure stability of the process.

### Cleanroom specifications

This product was manufactured in an ISO Class 7 Cleanroom. Monitoring of the Cleanroom is performed according to ISO14644-1.

### Validation JM BioConnect Film and components

The JM BioConnect Film is:

- compliant to European Pharmacopoeia ed. IV, 3.1.5;
- compliant to ISO 10993-4,-5,-6,-10,-11;
- USP class VI;
- USP<661> for plastic containers;
- animal derived component free (ADCF).

The used fluid path components:

- meet the USP class VI requirements for plastics;
- are animal derived component free (ADCF);
- are fabricated from medical grade materials in compliance with the US/FDA Regulations (21 CFR part 820).

### Sterilization

The components applied are compatible with gamma irradiation.

Quality Assurance Manager:

Medemblik, Date: JUNE 2017

Commissioned by JM Separations BV, Tilburg

### JM BioConnect

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JM BioConnect is a registered trade-name from JM Separations BV

