

Certificate of Compliance



500 L 3D Bag, 2 ports

1 pc. JMSCUC2V008201



**NON PYROGENIC / PYROGENFREI
SINGLE USE**

STERILE GAMMA



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.



103429100



2019/06



2022/06

0010

JM BioConnect® is a trade name of JM separations BV.

Certificate No.: 103429100

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.

Manager Quality Assurance:



Medemblik, date: 25 Jun 2019

Commissioned by JM Separations BV, Tilburg



JM BioConnect

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