

Certificate of Compliance



19L 2D Tankliner
1 pc. JMSCYA0V005100

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.



20170629-4



2017/06



2020/06

Certificate No.: 20170629-4

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 <87>; USP<88>;
- 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);

The tubing material used is in compliance with CFR 21 177.2600.

Sterilization

The components applied are compatible with gamma irradiation.

Quality Assurance Manager:

Tilburg, Date: JUNE-2017

Commissioned by JM Separations BV, Tilburg

JM BioConnect

Maidstone 50 • 5026 SK Tilburg • The Netherlands

T +31 (88) 5679500 • F +31 (88) 5679599 • info@jmbioconnect.com • www.jmbioconnect.com

CoC 24271752 • VAT NL803779781B01 • Bank Account 17.06.28.442 • IBAN NL51RABO0170628442

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