

RR Mechatronics Manufacturing B.V.

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De Corantiin 13 1689 AN ZWAAG The Netherlands

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Certificate of analysis

Product name:

Starrsed Control Level A

Article number:

QRR 049002

LOT number: Expiry date:

QCACF5AA2C 2025-03-23

LOT release date:

2023-12-22

|             | Specification | Validated value |
|-------------|---------------|-----------------|
| Value range | 30-60         | 34-54           |
| Mean value  | 40-50         | 44              |

The following information is provided by our OEM-manufacturer

- 1. No microbial contamination was recorded, as per quality control procedures
- 2. Fill volumes were verified to meet all specifications
- 3. Each human donor unit used to manufacture this product was tested and found non-reactive at the donor level per current applicable FDA requirements using FDA-accepted methods including testing for HIV-1/HIV-2 Antibody, HBsAg, HCV Antibody, HIV-1 and HCV by a nucleic acid test (NAT)
- 4. Batch uniformity studies verified product specifications were met

This lot of product has been controlled and approved for distribution.

For technical information and instructions for use regarding this product, refer to the Package

For safety related information regarding this product, refer to the Safety Data Sheet (SDS).

For questions about this certificate of analysis, please contact the Quality Assurance & Regulatory Affairs department at <a href="mailto:qara@rrmechatronics.com">qara@rrmechatronics.com</a>

Signed by:

Date:

QARA Department

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By the ORGALIME GENERAL CONDITIONS S2012 of March 2012. Any other conditions are herewith explicitly rejected by us. Conditions: ABN AMRO, Account number: 0403.537.037, Swift-address: ABNANL2A, IBAN: NL60 ABNA 0403 537 037

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