

RR Mechatronics Manufacturing B.V.

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Certificate of analysis

Product name: **Starrsed Control Level N**
Article number: **QRR 049001**
LOT number: **QCAB6AN505**
Expiry date: **2024-02-22**

LOT release date: 2022-11-29

	Specification	Validated value
Value range	1-15	1-10
Mean value	4-10	5

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 insert.

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

For questions about this certificate of analysis, please contact the Quality Assurance & Regulatory Affairs department at gara@rrmechatronics.com

Signed by: 

Date: 30-nov-2022

QARA Department

