

QUALITY CERTIFICATE

Products: Boule Con-Diff Tri-Level
Product Part Number: 502-012
Lot Number: 22409-6K
Expiration Date: 2025-01-31

Product	Vial Lot Number	Manufacture Date	Expiration Date
Boule Con-Diff Low	22409-61	2024-09-13	2025-01-31
Boule Con-Diff Normal	22409-62	2024-09-17	2025-02-04
Boule Con-Diff High	22409-63	2024-09-17	2025-02-04

CDS manufactures the products listed above under the jurisdiction of the US Food and Drug Administration (FDA).

CDS (Clinical Diagnostic Solutions Inc, Plantation, Florida) manufactures the products listed above for Boule Medical AB (Spanga, Sweden).

The above products were manufactured and analyzed in accordance with product specifications and quality control procedures and met all testing requirements.

The following additional information is provided:

1. No microbial contamination was recorded per quality control procedures.
2. Fill volumes were verified to meet all specifications.
3. **Handle as potentially infectious.** The human constituents have tested non-reactive for human Immunodeficiency Virus antibody (HIV), Hepatitis B Surface Antigen (HbsAg) and Hepatitis C Virus antibody (HCV).
4. Lot uniformity studies verified that product specifications were met and were maintained in vial to vial testing.
5. The animals used as donors were healthy and came from an USA APHIS (Animal and Plant Health Inspection System) certified facility.



Quality & Regulatory Department

10/18/24

Date

