**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-2016/266

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| **PRODUCT** | NUTRIFLEX(R) LIPID PERI | | REF. NO: NDQD201507001 |
| **DATE RECEIVED:** 02.07.2015 | **LABEL CLAIM:** | As specified in the attched form. | |
| **BATCH NO.:** 144818052 | **PRESENTATION:** | A sterile mixture for total parenteral nutrition presented in a 2500 mL flexible three chamber plastic bag. The lower compartment is filled with a 1000 mL solution of amino acids, the smaller upper compartment with the 500 mL of lipid emulsion and the other one with 1000 mL of glucose solution. | |
| **MGF. DATE:** - | **MANUFACTURER:** | B.BRAUN Medical (Pty) Ltd. | |
| **EXP. DATE:**  Oct.2016 | **ADDRESS:** | 253 Aintree Road North Riding 2194 | |
| **CLIENT REF NO:** | **CLIENT:** | B.BRAUN MEDICAL KENYA LTD 51200-00100 | |
|  | **TEST(S) REQUESTED:** | Sterility, Bacterial Endotoxin, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Sterility** | Membrane Filtration | BP 2016 Vol. V App XII C | No Microbial Growth | No Microbial Growth | **COMPLIES** |
| **Bacterial Endotoxin** |  | Manufacturer's In House Method | Not more than 2.00 EU/mL | 1.59 x 10-6 EU/mL | **COMPLIES** |
| **Assay** | Titration | Manufacturer's In House Method | 91.4 - 101.0 mMol/L | Total chlorides 94.5 mMol/L (RSD=0.3%, n=4) | **COMPLIES** |
| **Acidity/Alkalinity** | pH | BP 2016 Vol. V App XII C | 5.0 - 7.0:2.5 - 3.5:6.5 - 8.5:5.0 - 6.0 | Amino acid Compartment 5.6 | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Acidity/Alkalinity** | pH | BP 2016 Vol. V App XII C | 5.0 - 7.0:2.5 - 3.5:6.5 - 8.5:5.0 - 6.0 | Glucose Compartiment 3.1 | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Acidity/Alkalinity** | pH | BP 2016 Vol. V App XII C | 5.0 - 7.0:2.5 - 3.5:6.5 - 8.5:5.0 - 6.0 | Emulsion Compartiment 7.1 | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Acidity/Alkalinity** | pH | BP 2016 Vol. V App XII C | 5.0 - 7.0:2.5 - 3.5:6.5 - 8.5:5.0 - 6.0 | Mixture of All Compartments 5.4 | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |

**CONCLUSION:** The product complies with the specifications for the tests performed.

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| ANALYST: | ERIC NGAMAU |  | DATE:09-02-2016 |
| ANALYST: | DR. E. MUTUA |  | DATE:09-02-2016 |
| REVIEWER: | DR.ERNEST MBAE |  | DATE:09-02-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:02-12-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:03-01-2016 |