

TENDER CLARIFICATION

Letter of Impartiality

Bioworld Documented Context as Approved Service Provider to Multiple OEM's and Companies:

OBJECTIVE: This document serves as statement of objective impartiality with regards to Bioworld's technical support services for health technology devices to various medical equipment OEM's, distributors and suppliers as well as public and private institutions in South Africa and elsewhere.

Statement of Intent

Bioworld is a specialist multi-modality Biomedical Engineering service provider and does not distribute and or sell medical equipment. However, its infrastructure, educated and trained workforce, service-product packages as well as control systems are designed for the provision of HTM support systems inclusive of maintenance insofar medical equipment (as described and designated by the GMDN is concerned for which Bioworld holds a valid ISO13485 accreditation for this purpose. For this reason, Bioworld is tasked by OEM's, Suppliers and distributors to provide Biomedical Engineering services on behalf of themselves in the event where they have either limited to no infrastructure or capacity to provide maintenance an support services for the equipment they sell

Scope

Bioworld has an established control systems framework and infrastructure to support an array of needs of its customers, both public and private to provide maintenance support including technical support laboratories / workshops with a qualified and well trained workforce across South Africa to aid OEM's and distributors / suppliers in providing technical support for the equipment they sell to market.

These technical products and services includes the following:

- Technical audits and assessments of health technology
- General Preventive Maintenance of health technology devices
- General and acute corrective maintenance of health technology devices
- HTM Courses for customer technical and procurement staff
- Cloud based accessibility towards historical maintenance activity for all clients on the Bioworld EAM / CMMS control system.
- SAHPRA Suggested Regulatory Process Framework Compliant Control Systems
- GMDN Compliant Control Systems
- ISO13485:2016 Compliant Processes and Control Systems.

Normative Reference:

- **OEM** - Original Equipment Manufacturer.
- **HTM** – Health Technology Management
- **EAM** – Enterprise Asset Management.
- **CMMS** – Computerised Maintenance Management System.
- **GMDN** – Global Medical Device Nomenclature Database.
- **SAHPRA** – South African Health Products Regulatory Authority.

Statement of Impartiality

Bioworld remains impartial to any organisation to which it is linked through its service products and treats every customer's copyrights, trademarks, data and information with utmost confidentiality. For this reason it sometimes occur that Bioworld is approached by OEM's with similar products carrying exact designation assignments as per the GMDN.

This may lead to tender submissions where Bioworld may future as preferred technical support service provider on multiple tender submission from several companies as "sub Contractor".

In light of all the above, Bioworld would like to make it clear that it remains totally impartial from any tender submissions of it's clients and that it reserves the sovereignty of its intellectual property with regards to its accredited control systems, its processes and service offerings as its own indefinitely.

Yours Sincerely
Aslam Clarke - Director Operations
BioworldSA (PTY)Ltd.

