
Certificate of Approval

This is to certify that the Management System of:

Blue White Holdings (Pty) Ltd

Trading as: Blue White Medical (Pty) Ltd
Corner Fakkal & Jasmyn Street Factory 3, Silverton, Pretoria, 0184, South Africa

has been approved by LRQA to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 – 0054455

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

The scope of this approval is applicable to:

The repair and service of non-IVD capital medical devices and rigid and semirigid endoscopic. Management of outsourced manufacture and distribution of non-sterile patient comfort devices. Manufacture, assembly and distribution of X-ray Machine Stands and Carts used in Healthcare environment.

Luis Cunha

Area Operations Manager - North Asia & SAMEA

Issued by: LRQA Limited



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Certificate Schedule

Location	Activities
Corner Fakkal & Jasmyn Street Factory 3, Silverton, Pretoria, 0184, South Africa	ISO 13485:2016 The repair and service of non-IVD capital medical devices and rigid and semirigid endoscopic. Management of outsourced manufacture and distribution of non-sterile patient comfort devices.
Blue White Capital (Pty) Ltd. Corner Fakkal & Jasmyn Street Factory 3, Pretoria, 0184, South Africa	ISO 13485:2016 Manufacture, assembly and distribution of X-ray Machine Stands and Carts used in Healthcare environment. The repair and service of non-IVD capital medical devices.
Blue White Medical (Pty) Ltd. Corner Fakkal & Jasmyn Street Factory 3, Pretoria, 0184, South Africa	ISO 13485:2016 Management of outsourced manufacture and distribution of non-sterile patient comfort devices.
Blue White Optical (Pty) Ltd. Corner Fakkal & Jasmyn Street Factory 3, Pretoria, 0184, South Africa	ISO 13485:2016 The repair and service of rigid and semirigid endoscopic.

