

EC Certificate Full Quality Assurance System: Certificate ES04/61720

The management system of

Lodox Systems (Pty) Ltd

7 Dartfield Road, Kramerville, Johannesburg, 2146, South Africa

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

LODOX® eXero-dr and LODOX® Xmplar-dr, low-dose whole and partial body diagnostic X-ray imaging scanners for trauma and general radiography.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 30 November 2017 until 06 May 2021 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 06 May 2019

Issue 2. Certified since 06 May 2004

Certification is based on reports numbered ESMAD 209719

Authorised by

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