

EC Certificate Production Quality Assurance System: Certificate GB04/62626

The management system of

# Malosa Limited T/A Malosa Medical

Ashday Works Business Park, Elland, West Yorkshire, HX5 9JB, UK

has been assessed and certified as meeting the requirements of

## Directive 93/42/EEC on medical devices, Annex V

For the following products

**Sterile single use instruments and procedure packs for ophthalmology,  
gynaecology, reconstructive and general surgery.  
Sterile single use instruments for podiatry  
Non-sterile single use instruments for ophthalmology and general surgery**

**Annex V (sterility aspects only) - Restricted to the aspects of manufacture  
concerned with securing and maintaining sterile conditions:**

**Sterile single use instruments and procedure packs for ophthalmology  
Sterile single use instruments for podiatry, gynaecology, reconstructive  
and general non-invasive medical procedures.**

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

This certificate is valid from 07 June 2016 until 22 December 2020  
and remains valid subject to satisfactory surveillance audits.  
Re certification audit due before 01 December 2018  
Issue 10. Certified since 18 August 2004

Certification is based on reports numbered GB/PC 210127

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

202B Worle Parkway, Weston-super-Mare, BS22 6WA UK  
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 14 0215

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The management system of

# Malosa Limited T/A Malosa Medical

Ashday Works Business Park,  
Elland, West Yorkshire, HX5 9JB, UK

has been assessed and certified as meeting the requirements of

## ISO 9001:2008

For the following activities

**Manufacture of single use sterile disposable and non sterile instruments  
and procedure packs for the areas of ophthalmology, podiatry,  
gynaecology, reconstructive surgery, general surgery  
and non medical use.**

Further clarifications regarding the scope of this certificate and the applicability of  
ISO 9001:2008 requirements may be obtained by consulting the organisation

This certificate is valid from 22 December 2015 until 15 September 2018  
and remains valid subject to satisfactory surveillance audits.  
Re certification audit due before 15 September 2018  
Issue 9. Certified since 18 August 2004

Authorised by

SGS United Kingdom Ltd Systems & Services Certification  
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK  
t +44 (0)151 350-6666 f +44 (0)151 350-6600 [www.sgs.com](http://www.sgs.com)

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The management system of

# Malosa Limited T/A Malosa Medical

Ashday Works Business Park, Elland,  
West Yorkshire, HX5 9JB, UK



has been assessed and certified as meeting the requirements of

## ISO 13485:2003 EN ISO 13485:2012

For the following activities

**Manufacture of single use sterile disposable and non sterile instruments  
and procedure packs for the areas of ophthalmology, podiatry,  
gynaecology, reconstructive surgery and general surgery.**

This certificate is valid from 22 December 2015 until 22 December 2018  
and remains valid subject to satisfactory surveillance audits.  
Re certification audit due before 01 December 2018  
Issue 10. Certified since 18 August 2004

Authorised by

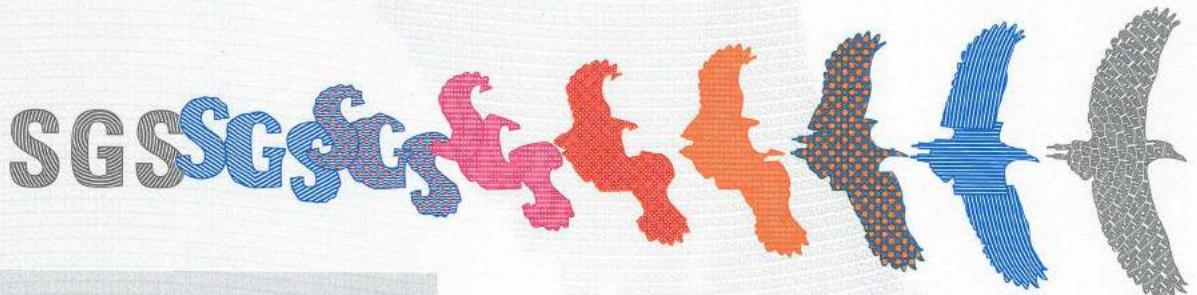


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SGS United Kingdom Ltd Systems & Services Certification  
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK  
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

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The management system of

# Malosa Limited T/A Malosa Medical

Ashday Works Business Park, Elland,  
West Yorkshire, HX5 9JB, UK



has been assessed and certified as meeting the requirements of

## ISO 13485:2003

For the following activities

**Manufacture of single use sterile disposable and non sterile instruments and procedure packs for the areas of ophthalmology, podiatry, gynaecology, reconstructive surgery and general surgery.**

Effective Date 22 December 2015 Expiry Date 22 December 2018  
Re certification audit due before 01 December 2018  
Valid subject to satisfactory surveillance audits.  
Issue 3. Certified since 22 December 2009

Authorised by  
Jan Saunders – Business Manager

SGS United Kingdom Ltd Systems & Services Certification  
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK  
t +44 (0)151 350-6666 f +44 (0)151 350-6600 [www.sgs.com](http://www.sgs.com)  
CMDCAS recognised registrar



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