

EC Certificate Production Quality Assurance System: Certificate EG19/19026

The management system of

# Afri Medical Company

Factory: Industrial Area C3, 10th of Ramadan City, Egypt

has been assessed and certified as meeting the requirements of

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

For the following products

**Sterile Blood Line, Sterile Fistula Needle,**

**Annex V Class I: "Sterility Aspects Only - Restricted To The Aspects Of  
Manufacture Concerned With Securing And Maintaining Sterile Conditions"  
Sterile Surgical Dressing And Sterile Incise Drape.**

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 18 May 2020 until 24 May 2024  
and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 10 January 2005  
and first certified by SGS Belgium NV since 16 January 2020

Certification is based on reports numbered EG/CAI/ PI211410

Authorised by

**SGS Belgium NV, Notified Body 1639**

SGS House Noorderlaan 87 2030 Antwerp Belgium  
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5008 - Certificate CE1639 AnnexV\_EN rev. 01

Page 1 of 1





EC Certificate Full Quality Assurance System: Certificate EG19/19027

The management system of

# Afri Medical Company

Factory: Industrial Area C3, 10th of Ramadan City, Egypt

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

**Sterile Haemodialysis Filters (Dialysers).**

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 18 May 2020 until 24 May 2024 and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 10 January 2005 and first certified by SGS Belgium NV since 16 January 2020

Certification is based on reports numbered EG/CAI PI211410

Authorised by

**SGS Belgium NV, Notified Body 1639**

SGS House Noorderlaan 87 2030 Antwerp Belgium  
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5007 - Certificate CE1639 Annex II-4\_EN rev. 02

Page 1 of 1

