

EC Certificate Full Quality Assurance System; Certificate ES19/86787

The management system of

A.J.COSTA (IRMÃOS), Lda

Estrada das Ligeiras, lote 10, Alto da Bela Vista
2735-337 CACEM, Portugal

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

The scope of registration appears on page 2 and 3 of this certificate.

This certificate is valid from 16 December 2019 until 20 June 2022
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 20 June 2008
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered ES/MAD 226551

Authorised by

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Certification Manager

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A.J.COSTA (IRMÃOS), Lda

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 1

Detailed scope

**Steam sterilizers, for sterilization of invasive and non invasive medical devices
and washer disinfectors for non invasive medical devices**

***Esterilizadores a Vapor para esterilização de dispositivos médicos invasivos e não
invasivos e Lavadores Desinfectadores para dispositivos médicos não invasivos***

Steam sterilizers

Amaro 5000 AJC 707070-1D GI
Amaro 5000 AJC 707070-2D GI
Amaro 5000 AJC 7070100-1D GI
Amaro 5000 AJC 7070100-2D GI
Amaro 5000 AJC 7070125-1D GI
Amaro 5000 AJC 7070125-2D GI
Amaro 5000 AJC 7070130-1D GI
Amaro 5000 AJC 7070130-2D GI
Amaro 5000 AJC 7070150-1D GI
Amaro 5000 AJC 7070150-2D GI
Amaro 5000 AJC 7070160-1D GI
Amaro 5000 AJC 7070160-2D GI
Amaro 5000 AJC 7070190-1D GI
Amaro 5000 AJC 7070190-2D GI

Amaro 5000 AJC 707070-1D SG
Amaro 5000 AJC 707070-2D SG
Amaro 5000 AJC 7070100-1D SG
Amaro 5000 AJC 7070100-2D SG
Amaro 5000 AJC 7070125-1D SG
Amaro 5000 AJC 7070125-2D SG
Amaro 5000 AJC 7070130-1D SG
Amaro 5000 AJC 7070130-2D SG
Amaro 5000 AJC 7070150-1D SG
Amaro 5000 AJC 7070150-2D SG
Amaro 5000 AJC 7070160-1D SG
Amaro 5000 AJC 7070160-2D SG
Amaro 5000 AJC 7070190-1D SG
Amaro 5000 AJC 7070190-2D SG
Amaro 5000 AJC 7011280-1D SG
Amaro 5000 AJC 7011280-2D SG

A.J.COSTA (IRMÃOS), Lda

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 1

Detailed scope

Amaro 5000 AJC 70112110-1D SG
 Amaro 5000 AJC 70112110-2D SG
 Amaro 5000 AJC 70112150-1D SG
 Amaro 5000 AJC 70112150-2D SG
 Amaro 5000 AJC 70112220-1D SG
 Amaro 5000 AJC 70112220-2D SG
 Amaro 5000 AJC 90145130-1D SG
 Amaro 5000 AJC 90145130-2D SG
 Amaro 5000 AJC 90145240-1D SG
 Amaro 5000 AJC 90145240-2D SG

Steri 21 AJC 404066-1D GI
 Steri 21 AJC 404066-2D GI
 Steri 21 AJC 505066-1D GI
 Steri 21 AJC 505066-2D GI
 Steri 21 AJC 5050100-1D GI
 Steri 21 AJC 5050100-2D GI

Steri 21 AJC 404066-1D SG
 Steri 21 AJC 404066-2D SG
 Steri 21 AJC 505066-1D SG
 Steri 21 AJC 505066-2D SG
 Steri 21 AJC 5050100-1D SG
 Steri 21 AJC 5050100-2D SG

Washer disinfectors

Eco 25
 Ld 21