

EC Certificate Full Quality Assurance System: GB08/74122

The management system of

PROHS Equipamento Hospitalar e Serviços Associados SA

Rua do Castanhal 316 - Zona Industrial Maia I,
sector II, 4475-122 Maia, 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 of this certificate.

This certificate is valid from 21 August 2014 until 20 February 2019 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 20 February 2017
Issue 9. Certified since 20 February 2008

Certification is based on reports numbered GB/PI 217699

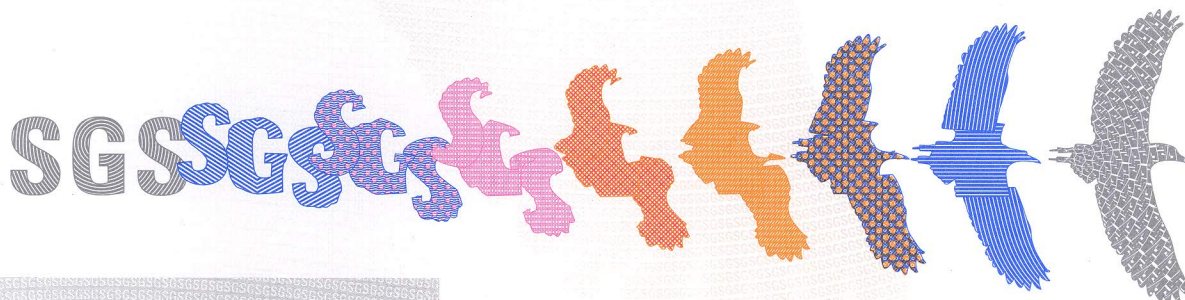
Authorised by

SGS United Kingdom Ltd, Notified Body 0120

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PROHS Equipamento Hospitalar e Serviços Associados SA

Directive 93/42/EEC on medical devices, Annex II (excluding section 4)

Issue 9

Detailed scope

Steam Sterilizers:

Full Jacket:

- FJ 70L 1/2 PD (32*32*70)
- FJ 100L 1/2 PD (32*32*100)
- FJ 110L 1/2 PD (40*40*70)
- FJ 145L 1/2 PD (40*40*90)
- FJ 175L 1/2 PD (50*50*70)
- FJ 250L 1/2 PD (50*50*100)
- FJ 340L 1/2 PD (70*70*70)
- FJ 360L 1/2 PD (60*60*100)
- FJ 490L 1/2 PD (70*70*100)
- FJ 610L 1/2 PD (70*70*125)
- FJ 640L 1/2 PD (70*70*130)
- FJ 740L 1/2 PD (70*70*150)
- FJ 780L 1/2 PD (70*70* 160)
- FJ 930L 1/2 PD (70*70*190)

Partial Jacket

- PJ 190L 1/2 PD (50*50*75)
- PJ 250L 1/2 PD (50*50*100)
- PJ 325L 1/2 PD (50*50*130)
- PJ 460L 1/2 PD (68*68*100)
- PJ 600L 1/2 PD (68*68*130)
- PJ 740L 1/2 PD (68*68*160)

Washer Disinfectors for non-invasive devices

Mod. GI

Mod. JA

Mod. JM

For placing on the market of Class III devices covered by this certificate, an EC Design Examination Certificate according to Annex II (Section 4) is required.